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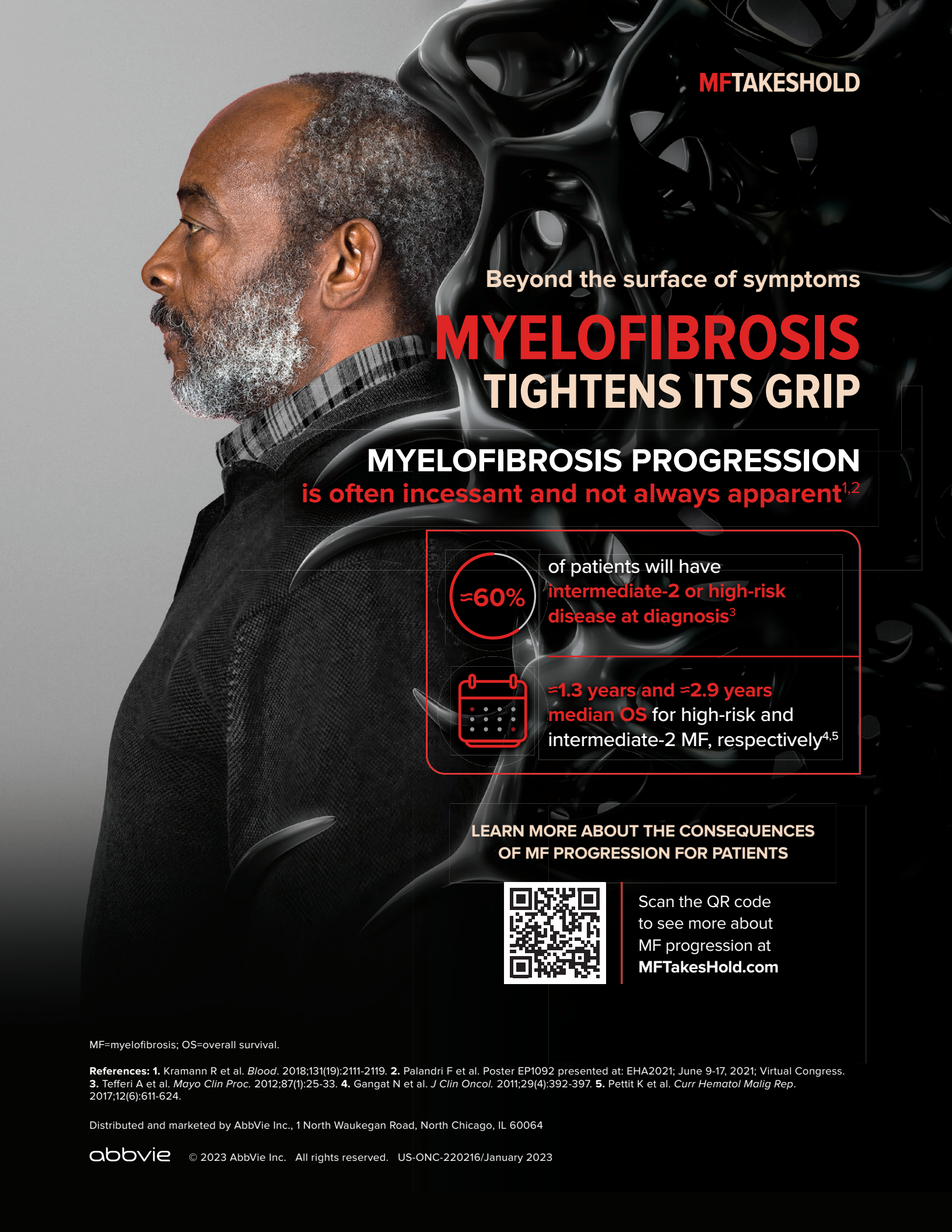
20th Annual Indy Hematology Review™

Saturday, Match 18th 2023

JOURNAL OF INDY HEMATOLOGY REVIEW 2023



MF=myelofibrosis; OS=overall survival.

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CHAIRMAN'S LETTER

20 YEARS OF LOVE AND MENTORS, ... THE IMPROBABLE JOURNEY

June 1986, the Hippocratic oath, then on to graduation from medical school! Exciting, scary, NOW what? Looking backwards now, I remember feeling accomplished but also lost, wandering what journey lies ahead. How much further, how much longer and how much more?

Day dreaming was my favorite past time as a child, staying awake and dreaming about faraway places and just imagining my greatest joys. And now, I realize I am an adult, and I am still dreaming. Four years later, after internship, after National service and primary care, and I am in the greatest country on earth.

Then, it is the greatest love of my life, but also, almost immediately snatched and taken away from me. But life happens and that improbable journey continues. Medical science is personal for me.

In 2003, the leading stories were the emergence of monoclonal antibodies for lymphoma, leukemia and of proteasome inhibitors for myeloma. Two decades later, its more complicated, but also more exciting; more monoclonal antibodies, tyrosine kinase inhibitors, Bruton's tyrosine kinase inhibitors, antibody-drug/radionuclide conjugates, T-cell directed therapies, safer and yet more effective hematopoietic stem cell therapies. Sophisticated, effective, and many more lives saved. Yes, improving outcomes through science and education today.

Mentors and friends
Mentors are the blood of renewal, courage, and kinetic energy, moving forward constantly with that nervous tick, but onward and onward.

I have been blessed with great mentors, too many to list but blessed to remember: Ejedafeta, Neeta, Mable, John, Georgia, Robert, T. Howard but the list goes on.

20 years ago, Indy Hematology Review was created, today we celebrate education, learning and our great faculty.

20 years of ongoing friendships… OUR FRIENDS; Mike, Ken, Steve, Steve, Dick, Rick, Rich, Uncle Rick, Rob, Ayelew, Craig, Ruben, Rami, Wendy, Hagop, Adrian, Sonali, Sandra, Jennifer, Dave, Kristie, Charlie, Morie, Martin, Bruce, Harry, Gilles, Bill, Bill, Joe, Saad, Bryan, Sumeet …..

20 years later, I continue to celebrate more than two decades of life, of a great love story of my beloved, beautiful, tenacious, and courageous wife, and Chief Operating Officer, DONNA Marie "Orezeme" (My soul spirit) Birhiray, my family and wonderful children. And our wonderful board of directors; Mike, Donna, Jennifer, and Thalia, THANK YOU for your uncompensated, selfless dedication, devotion, time, and your energies.

20 years of learning and achieving tomorrows' goal through education today, for OUR PATIENT'S and ourselves.

Thank you to our industry partners and sponsors particularly our name sponsor: COMMUNITY HEALTH NETWORKS.

Thank you for our 20 years!!!!!! And see you next year when we can DRINK… 21 years and counting on **February 24, 2024**, INDY HEMATOLOGY REVIEW 2024.

Now what? "Onward and forward, questing for EDUCATION, EQUITY and JUSTICE whilst achieving tomorrow's outcomes today". See you in 2024!

Thank You,
Ruemu E. Birhiray, MD
Chair, Indy Hematology Review

SYMPOSIUM AGENDA

SATURDAY, MARCH 18, 2023

All sessions are in Grand Ballroom 4-5 (2nd Floor) unless otherwise noted

6:30 a.m. – 10:00 a.m.	**Registration** | Grand Ballroom Foyer
7:00 a.m. – 7:45 p.m.	**Breakfast Product Theaters** | Cameral, Council (1st Floor) and House (2nd Floor)
7:00 a.m. – 4:00 p.m.	**Exhibitor Displays** - **Coffee** | Grand Ballroom 1-3
7:55 a.m. – 8:20 a.m.	**State of the Art: 2023: Emerging Therapies in Hematologic Malignancies** | Ruemu Birhiray, MD, Chairman
8:20 a.m. – 8:30 a.m.	**Conversations with the 2023 President of the American Society of Hematology** | Robert Brodsky, MD
8:30 a.m. – 9:00 a.m.	**Improving Outcomes with Current Therapies in Acute Myeloid Leukemia and Acute Promyelocytic Leukemia: What We Recommend in 2023 |** Martin Tallman, MD
9:00 a.m. – 9:30 a.m.	**Apollo and The Indianapolis Oracle: Prognostication and Treatment of Myelodysplastic Syndromes** | Richard Stone, MD
9:30 a.m. – 10:00 a.m.	**Treatment Goals in Chronic Myeloid Leukemia: Managing Resistance, Recurrence and Discontinuation** | Richard Larson, MD
10:00 a.m. – 10:15 a.m.	**Coffee Break – Exhibit Hall** | Grand Ballroom 1-3
10:15 a.m. – 10:45 a.m.	**Emerging and Current Treatment of Multiple Myeloma: What Should We Know and What Should We Do?** | Kenneth Anderson, MD
10:45 a.m. – 11:15 a.m.	**Hematopoietic Transplantation and Cellular Therapies** | Richard Childs, MD
11:15 a.m. – 11:45 a.m.	**Managing the Benign Hematology Consult: Treatment Recommendations for Coagulopathy, Cytosis and Cytopenia** | Craig Kessler, MD, MACP
11:45 a.m. – 12:00 p.m.	**Coffee Break – Exhibit Hall** | Grand Ballroom 1-3
12:00 p.m. – 12:30 p.m.	**Myelofibrosis Chronic and Blast Phase: 2023 Algorithms for Risk Stratification and Treatment** | Ayalew Tefferi, MD
12:30 p.m. – 1:00 p.m.	**Polycythemia Vera, Philadelphia Chromosome Negative Myeloproliferative and FGFR Mutant Myeloid Neoplasms** | Angela Fleischman, MD, PhD
1:00 p.m. – 1:45 p.m.	**Luncheon Product Theaters** | Capitol 1 & 3, Cameral, Council, (1st Floor) House (2nd Floor)
1:45 p.m. – 2:00 p.m.	**Coffee Break – Exhibit Hall** | Grand Ballroom 1-3
2:00 p.m. – 2:45 p.m.	**T. Howard Lee Keynote Lecture: 20 Years of Indy Hematology Review and The Cure is in: Managing Indolent and Mantle Cell Lymphomas with Targeted and Cellular Therapies in 2023** | Gilles Salles, MD, PhD
2:45 p.m. – 3:15 p.m.	**Current Controversies and Recommendations for the Treatment of Acute Lymphoblastic Leukemia and Lymphoblastic Lymphoma: The Indy Hematology Review Recommendations for 2023** | Wendy Stock, MD, MA
3:15 p.m. – 3:45 p.m.	**Emerging Therapy for Relapsed and Refractory Chronic Lymphocytic Leukemia** | William Wierda, MD, PhD
3:45 p.m. – 4:00 p.m.	**Coffee Break – Exhibit Hall** | Grand Ballroom 1-3

SYMPOSIUM AGENDA

SATURDAY, SEPTEMBER 10, 2022

All sessions are in Grand Ballroom 4-5 (2nd Floor) unless otherwise noted

4:00 p.m. – 4:30 p.m.	**Annual Steven Coutre Chronic Lymphocytic Leukemia Memorial Lecture: Therapeutic Options in CLL in 2023: Choosing Wisely: Initial Therapy in CLL** | Jennifer Woyach, MD
4:30 p.m. – 5:00 p.m.	**Jumping On a Moving Train: Emerging and Current Treatment for Hodgkin's Lymphoma** | Matthew Lunning DO, FACP
5:00 p.m. – 5:30 p.m.	**Advancing Therapeutic Outcomes in Aggressive B and T Cell Lymphomas** | Tycel Phillips, MD
5:30 p.m. – 6:00 p.m.	**Beyond Hyperviscosity: 80 Years and Counting, Treatment of Waldenström's Macroglobulinemia** | Steven Treon, MD, MA, PhD, FACP, FRCP
6:00 p.m. – 6:30 p.m.	**The Great Debate: Controversies in The Initial Therapy of Multiple Myeloma: To Transplant or Not When Minimal Residual Disease has been Achieved as Initial Therapy for Multiple Myeloma: Monitoring and Rescuing the MRD Negative Patient with Multiple Myeloma After Initial Therapy** | Joseph Mikhael MD, MEd, FRCPC, FACP **Transplanting the MRD Negative Myeloma Patients for a Deeper Remission After Initial Therapy** | Saad Usmani, MD, MBA, FACP
6:30 p.m. – 7:00 p.m.	**Q/A and Panel Discussion – Take Home Messages: Achieving Tomorrow's Outcomes Through Education Today** Ruemu E. Birhiray, MD – Chair and Moderator Michael Wiemann, MD, FACP – Co-Chair William Wierda, MD, PhD – Chronic Lymphocytic Leukemia Rami Komrokji, MD – Acute Leukemias and Myelodysplastic Syndromes Ruben Mesa, MD, FACP – Myeloproliferative Neoplasms Charles Schiffer, MD – Acute Lymphoblastic Leukemia Morie Gertz, MD, MACP – Plasma Cell Neoplasms and Amyloidosis
7:00 p.m. – 7:30 p.m.	**Town Hall Reception** | Grand Ballroom Foyer
7:30 p.m. – 8:45p.m.	**Hematologic Malignancies Town Hall** Ruemu E. Birhiray, MD – Chair and Moderator Michael Wiemann, MD, FACP – Co-Chair Morie Gertz, MD, MACP – Plasma Cell Disorders and Amyloidosis Jennifer Woyach, MD – Chronic Lymphocytic Leukemia Rami Komrokji, MD – Acute Leukemias and Myelodysplastic Syndromes Ruben Mesa, MD, FACP – Myeloproliferative Neoplasms Tycel Phillips, MD – Lymphomas Matthew Lunning, DO, FACP - Lymphomas Saad Usmani, MD, MBA, FACP – Multiple Myeloma Charles Schiffer, MD – Acute Lymphoblastic Leukemias Joseph Mikhael, MD, MEd, FRCPC, FACP – Multiple Myeloma Steven Treon, MD, MA, PhD, FACP, FRCP – Waldenström's Macroglobulinemia

NURSING/ALLIED PROVIDERS AGENDA

SATURDAY, MARCH 18, 2023

All sessions are scheduled in Capitol Ballroom 2 (1st Floor) unless otherwise noted
Moderators: Donna M. Birhiray, OTR, MBA | Thalia Hammond

6:30 a.m. – 10:00 a.m.	**Registration** | Grand Ballroom Foyer
7:00 a.m. – 7:45 p.m.	**Breakfast Product Theaters** | Cameral, Council (1st Floor) and House (2nd Floor)
7:00 a.m. – 4:00 p.m.	**Exhibitor Displays** - **Coffee** | Grand Ballroom 1-3
7:55 a.m. – 8:20 a.m.	**State of the Art: 2023: Emerging Therapies in Hematologic Malignancies** Ruemu Birhiray, MD, Chairman | Grand Ballroom 4-5
8:20 a.m. – 8:30 a.m.	**Conversations with the 2023 President of the American Society of Hematology** | Robert Brodsky, MD
8:40 a.m. – 9:05 a.m.	**Understanding and Managing Immune Effector Toxicities in Hematologic Toxicities** | David Reeves, PharmD, BCOP
9:05 a.m. – 9:30 a.m.	**Management of Long-Term Survivors of Hematologic Malignancies** | Sandra Garofalo, MS, APRN, AOCNP
9:30 a.m. – 10:00 a.m.	**Managing Disorders of the Benign Hematology Patient** | Craig Kessler, MD
10:00 a.m. – 10:15 a.m.	**Coffee Break – Exhibit Hall** | Grand Ballroom 1-3
10:15 a.m. – 10:45 a.m.	**Understanding the Diagnosis and Treatment of Plasma Cell Disorders** | Saad Usmani, MD, MBA, FACP
10:45 a.m. – 11:15 a.m.	**Emerging and Current Treatment of Amyloidosis and Waldenstrom's Macroglobulinemia** | Morie Gertz, MD, MACP
11:15 a.m. – 11:30 a.m.	**Coffee Break – Exhibit Hall** | Grand Ballroom 1-3
11:30 a.m. – 11:55 a.m.	**Recognizing Toxicities of Oral Oncolytics in the Management of Hematologic Malignancies** | Kristi Orbaugh, RN, MSN, RNP, AOCN
11:55 a.m. – 12:25 p.m.	**Diagnosis and Treatment of Myeloproliferative Neoplasms** | Ruben Mesa, MD, FACP
12:25 p.m. – 12:55 p.m.	**Current and Emerging Therapies for Acute Leukemias and Myelodysplastic Syndromes** | Richard Larson, MD
12:55 p.m. – 1:00 p.m.	**Q & A Session**
1:00 p.m. – 1:45 p.m.	**Luncheon Product Theaters** | Capitol 1 & 3, Cameral, Council, (1st Floor) House (2nd Floor)
1:45 p.m. – 2:00 p.m.	**Coffee Break – Exhibit Hall** | Grand Ballroom 1-3
2:00 p.m. – 9:00 p.m.	Join the sessions in Grand 4 -5 to complete the day

Meet Svitlana Fomina, MD: This Year's Scholarship Recipient

Written by Nicola Donelan

Dr. Svitlana Fomina is an oncologist at the Regional Oncology Center and a director at the Doctor Alex Expert Medical Center, Kharkiv, Ukraine. She is the recipient of a scholarship that will enable her to attend the 20th annual Indy hematology review on March 18, 2023 in Indianapolis, USA.

In a recent interview conducted via email, we were able to briefly find out about her training to become an oncologist, her support system, the challenges she faces in the Ukraine, and her plans for using the information learned at the Indy Hematology Review to improve the quality of patient care in her country.

Dr. Fomina graduated from Kharkiv Medical university and became an oncologist in 1995. Over the course of her career she continues expanding her qualifications through continuing medical education seminars. Svitlana's husband and fourteen-year-old daughter have been instrumental as a support system in her professional endeavors.

In her field Dr. Fomina sees advancements in diagnostic methods for early detection of oncological diseases and precursors to cancer as beneficial for doctors in her profession. However, over the last year, the greatest challenge has been maintaining optimal level of care for patients despite the ongoing war.

Dr. Fomina is very excited to learn about new methods and exchange experiences with the doctors she may have the opportunity of meeting. She is also looking forward to being shown new research, as well as get a firsthand look into medical advances in the United States. Gaining access to new publications at this meeting would also be extremely useful for broadening her knowledge base.

Participating in 20th Indy Hematology Review will expand Dr. Fomina's horizons. She is particularly interested in Dr. Tefferi's presentation on risk stratification and treatment. In meeting with fellow oncologists, it is Svitlana's hope to widen her knowledge base. She believes that being in the presence of fellow professionals will reinvigorate her drive despite difficulties brought on by the war. Expanding her knowledge about new diagnostic methods will go a long way to assist patients back in Ukraine.

Svitlana is looking forward to sharing materials and knowledge she acquires at the conference to disseminate new discoveries in protocols and treatment methods upon her return to the Ukraine. She will be collaborating with oncologists in Ukraine to proliferate advances in medical oncology from colleagues in US.

Presentation Slides

Faculty Presentation slides (as permitted by each faculty member) are available at:
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An Interview with Sumeet Bhatia, MD
Life-long Learning, being a Team Player, and Providing Patient-Centric Care

Written by Nicola Donelan

Dr. Bhatia is a board-certified physician in medical oncology, hematology, and internal medicine at the Community Health Network in Indiana. He graduated from the University of Bombay Medical College, Bombay, India, and completed his residency in internal medicine at the University of Connecticut School of Medicine, Farmington, with a fellowship in hematology/oncology at the Indiana University School of Medicine, Indianapolis. In a recent interview with Dr. Bhatia, he shared his views on how to achieve a rewarding career, what motivates him and also his perspectives on the current state and what's in store for the future of hematology oncology.

Steps along the journey to becoming a hematologist oncologist.

During Dr. Bhatia's residency in India, he took care of kids with acute lymphoid leukemia in situations which were fairly primitive. Regardless of the conditions, he was able to see good outcomes for his patients and this encouraged him to pursue specializing in liquid tumors, lymphoma, leukemia, and bone marrow transplants. ***"My interest in this field led me to a fellowship at Indiana University (IU) where Dr. Larry Einhorn influenced me to become a hematologist oncologist, and, according to him, he showed me the light that the way to treat people was not to give high doses of chemotherapy and do a bone marrow transplant, but to use more targeted therapies,"*** he recalled. The progress in treatment modalities for many hematologic diseases today allows some patients to avoid chemotherapy all together he further explained.

When he completed the fellowship, Dr. Bhatia stayed at the IU health system and then in 2003, he came to Community Health Network. Dr. Bhatia eventually moved his entire practice to Community Health Network in 2012 heavily influenced by Bryan Mills the CEO of Community Health Network, who at that time, was launching a collaboration with MD Anderson. The Community Health Network and MD Anderson Cancer Center formed a partnership, resulting in one of the world's largest and most respected cancer centers. Dr. Bhatia highlighted the fact that MD Anderson encourages not only specialty care, but sub-specialization. "I take care of a lot of patients with acute leukemia, lymphoma, myeloma, melanoma, and brain tumors, and that sub-specialization has helped for us to dive deep and narrow which actually I believe allows for best patient care" explained Bhatia.

An exciting and rewarding field that requires teamwork.

"During the last 20 years there has been an incredible amount of progress. Today, we treat and cure people who once upon a time were considered to be unsalvageable," said Dr. Bhatia. If one compares the rapid progress made in hematology oncology to the slow progress in cardiology over the same time period, it highlights this even more. "US mortality rates in the last 10 years have dropped by 30 to 40% in cancer care, and we live in an amazing time for cancer care with all the cutting-edge technology and resources that are available," he further pointed out. According to Dr. Bhatia, a career in hematology oncology allows you to balance a great life which is very rewarding.

Delivering care these days has become very complicated and requires teamwork with physicians, nurse practitioners, nurses, pharmacists, social workers all coming together described Bhatia. "At Community Health network, we've been able to create such teams to deliver care. It is essentially become a hybrid of patient-centric care which people associate with communities, aligned with excellence in care, that people associate with academia," said Dr. Bhatia, who believes that this type of ideal model has been realized through the Community Health Network - MD Anderson partnership. "A modern physician is almost like a team leader, he doesn't have to know everything, but he must be able to use good judgment, and use his team to deploy the best care," said Dr. Bhatia.

Timing of care is as important as availability of therapies.

There are many treatments out there for patients with hematologic malignancies including transplant, CAR-T, and targeted therapies such as BTK inhibitors and bispecific antibodies. When used correctly these therapies can result in extended life expectancy and even cures for some

explained Dr. Bhatia. ***"One does have to recognize that there is a sense of urgency to allow patients access to therapies and the timing of treatment can actually be as important as access to these new therapies, because once a body gets damaged it is difficult to salvage, and these diseases change rapidly in a person," he emphasized. "It's not only a science issue, but it's a health care delivery issue,"*** he said.

Giving an example, Dr. Bhatia described that if a patient is already in organ failure before you get to them, it's very difficult to take care of them, even with the most sophisticated therapies. He strongly believes that patients should not have to leave their community for cutting-edge care.

Relevant training and life-long education will never be replaced by technology.

When Dr. Bhatia was asked to give some advice to medical students interested in pursuing hematology oncology as a career, he first mentioned that thoroughly exploring the field is very important, so that you are sure that you like it before deciding to do it. Being a hematologist oncologist requires life-long learning especially because the field is changing so rapidly. ***"The concept of your job description is going to change,"*** he explained. However, there are some skills that will always be used such as soft skills like being able to take a proper history, getting hidden information from your patients, and competent bedside manners. ***"AI, ChatGPT and algorithms will never replace these soft skills,"*** said Bhatia.

In Dr. Bhatia's opinion, training new hematologist oncologists requires more of a focus on internal medicine. "Internal medicine training is one of the bedrocks of delivering good care in hematology oncology," he explained. He believes that care must be taken when physicians become too sub-specialized and lose sight of the big picture because understanding all the other organs is critical for overall patient care.

About 5 years ago the Community Health Network decided that they would sponsor the Indy Hematology Review and have supported this meeting ever since then. The ongoing training, learning, and networking opportunities that the Indy Hematology Review provides is a valuable resource that continues to benefit the local Indiana communities.

"We felt this was a cutting-edge review that met the needs of the State and met a vital need for our community and for our physicians. Through education, you take care of patients, and the standard of care is changing so fast that we could not lose this resource locally," said Bhatia.

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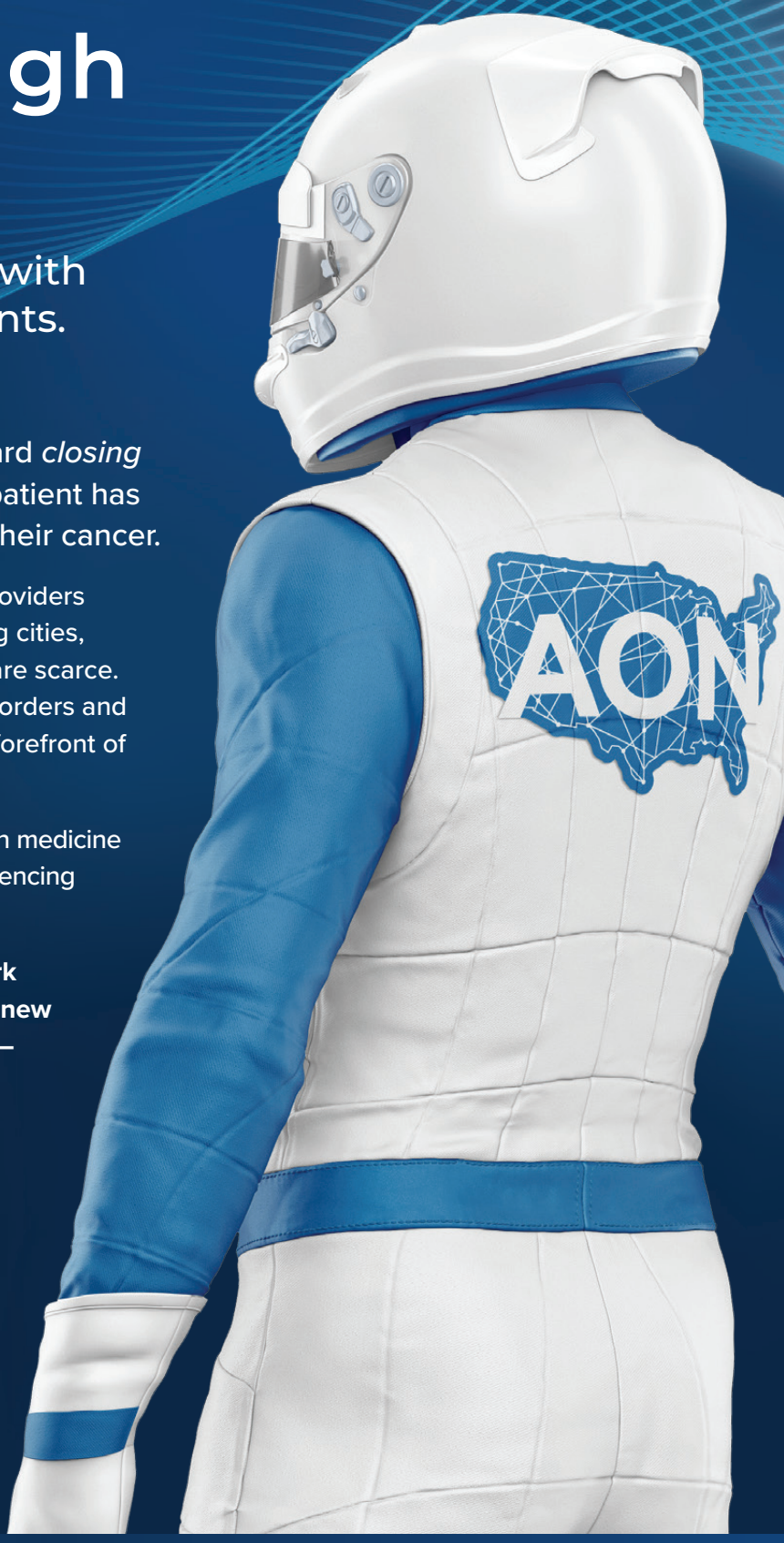

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2023 FACULTY AND ABSTRACTS

Ruemu E. Birhiray, MD

Emerging Therapies in Hematologic Malignancies and Disorders: Indy Hematology Review 2023 Abstract

In the past year, significant and clinically meaningful improvements have occurred in the treatment of hematologic malignancies and disorders. The most impactful abstracts presented since September 2022 at major meetings will have the following effects on clinical practice.

Immediately Practice changing: Blinatumumab + Chemotherapy Consolidation in MRD negative Ph Negative ALL.

Ponatinib plus reduced intensity chemotherapy in Ph positive ALL.

Avoiding remission induction and proceeding with immediate allotransplantation in Relapsed/ Refractory AML.

MATRix chemotherapy followed by HDC/ASCT in Primary CNS lymphoma.

Ibrutinib + chemoimmunotherapy as substitute for ASCT in younger patients with MCL.

Iptacopan in Paroxysmal Nocturnal Hemoglobinuria with residual anemia residual anemia on anti-C5 therapy.

Data with Practice Confirming effects include: Gemtuzumab Ozogomycin in patient's aged 18-60 years with NPM-1 mutant AML, Post-Transplant Cyclophosphamide + TAC + MMF vs TAC + MTX for Prevention of GVHD following Reduced-Intensity conditioning allogeneic SCT, Covalent BTKi therapy in CLL: Zanabrutinib

Data with Potentially Practice Changing effects include: Pirtobrutinib in relapsed and refractory Waldenström Macroglobulinemia, Efgartigimod in Adult Primary Chronic or Persistent ITP, GPCR5D x CD3 Bispecific antibody Talquetamab in RRMM

Emerging data to stay tuned for include: Asciminib in patients failing to reach molecular targets in CML after initial TKI therapy, CD20 x CD3 Bispecific antibodies plus chemo-immunotherapy as initial therapy for DLBCL, Bispecific antibodies in R/R lymphoma and RRMM, Polatuzumab Vedotin + R-ICE (PolaR-ICE) As Second-Line Therapy in R/R DLBCL, Epcoratimab for Richter's transformation in CLL.

References: PRACTICE CHANGING ABSTRACTS

1. Litzow. ASH 2022. Abstr LBA1.
2. Jabbour et al. ASCO 2023 Monthly Plenary Series, Journal of Clinical Oncology 41, no. 36_suppl (January 20, 2023) 398868-398868. Published online February 17, 2023.
3. Stelljes. ASH 2022. Abstr 4.
4. Illerhaus. ASH 2022. Abstr LBA-3.
5. Dreyling. ASH 2022. Abstr 1.
6. De Latour. ASH 2022. Abstr LBA-2

Kenneth Anderson, MD

Kraft Family Professor of Medicine, Harvard Medical School, Program Director of the Lebow Institute for Myeloma Therapeutics and Jerome Lipper Multiple Myeloma Center, Dana-Farber Cancer Institute (Boston, MA)

Over the last four decades, he has developed laboratory and animal models of myeloma in its microenvironment which have allowed for both identification of novel targets and validation of novel targeted therapies. He has then rapidly translated these studies to clinical trials culminating in FDA approval of novel targeted therapies, which have markedly improved patient outcome.

Emerging and Current Treatment of Multiple Myeloma: What Should We Know and What Should We Do?

There are 16 novel agents and 31 FDA approved treatment regimens for multiple myeloma (MM) which have transformed therapy, achieved high frequency and extent of response, and markedly improved patient outcomes. Minimal residual disease (MRD) negativity is commonly achieved either in newly diagnosed (ND) or in relapsed refractory (RR) MM and is associated with prolonged progression free (PFS) and overall survival (OS). In the future, mass spectroscopy will specifically detect monoclonal proteins with increased sensitivity and single cell genomic profiling of both circulating tumor cells (CTCs) and immune cells will be useful for prognosis and defining response to therapy. Earlier intervention in high-risk smoldering MM with lenalidomide (R) or dexamethasone (d) can delay progression to active disease; protocols evaluating daratumumab (Dara), lenalidomide (R), bortezomib (V), dexamethasone (d), autologous stem cell transplant (ASCT), and novel immune therapies are similarly directed to delay or even prevent development of active MM. RVd and early ASCT followed by continuous R maintenance achieves prolonged PFS and OS; moreover, DaraRVd before and after ASCT followed by DaraR maintenance induces MRD responses in most patients. Carfilzomib (K) Rd and DaraKRd in the ASCT paradigm similarly achieve high frequency of MRD responses. In the future, MRD will inform therapy: early studies suggest that maintenance therapy may be discontinued in the setting of persistent MRD in patients with 0 or 1 genetic abnormality (CA), but not in those patients with additional CA. In newly diagnosed transplant-ineligible, including frail, patients, DaraRD prolongs both PFS and OS. Relapsed MM treatment is informed by frailty status, comorbidities, risk assessment, treatment history, and therapeutic goals. Triplet therapies incorporating pomalidomide (P) and/ or K include DaraPd, isatuximabPd, KPd, elotuzumabPd, DaraKd, and isatuximab Kd. Treatments for triple class refractory MM include belantomab mafodotin, Idecel and Ciltacel CAR T cells, and bispecific T cell engager (BiTE) teclistamab. CAR T cells achieve remarkable responses in RRMM patients with 4 or more prior therapies and are under evaluation earlier in the disease course. Additional targets (i.e., GPRC5D) and constructs (i.e., PHE 885, CC-98633, BAT CAR) will allow for their more widespread availability. BiTEs achieve remarkable responses in RRMM; additional targets ((i.e., GPRC5D), constructs (i.e., trispecific engagers), and their earlier use will improve outcomes. Importantly, combination

therapies ((i.e., CAR T and BiTEs with R or with each other) are under evaluation. Finally, improved use of known agents and identification of new Achilles heels in MM is critical for future progress. The induction of immunogenic cell death (ICD) by known MM agents, i.e., bortezomib, confers improved prognosis; conversely, developing strategies to restore ICD in high risk MM will address this unmet medical need. Preclinical studies have also recently identified novel targets to overcome immunosuppression (i.e., PHF 19) and resistance to immunotherapy (i.e., KDM 6A). In the future, Dara RVD will achieve high rates of MRD- response in NDMM; and then CAR T cells and/or BiTEs with or without ASCT will be used to achieve persistent MRD responses and memory anti-MM immunity. This will allow patients to be disease free and off all therapy.

Robert Brodsky, MD
Hopkins Family Professor, Director of the Division of Hematology, Johns Hopkins University, 2023 President of the American Society of Hematology (Baltimore, MD)

Richard Childs, MD
Clinical Director, National Heart, Lung, and Blood Institute (NHLBI) at the National Institutes of Health (NIH), (Bethesda, MD)

Dr. Childs oversees one of the NIH's largest clinical and translational science programs, directing an office with more than 160 staff members who have oversight of approximately 350 clinical researchers conducting over 250 investigator-initiated clinical trials.

Hematopoietic Transplantation and Cellular Therapies
The results of Allogeneic Hematopoietic Stem Cell Transplantation (ASCT) have improved greatly over the past 2 decades. During this session, Dr. Childs will highlight refinements in allogeneic transplant approaches that have improved transplant outcomes including the use of reduced intensity conditioning, better antiviral therapies, better agents to prevent and treat graft-vs-host disease that have all played a role in reducing the risk of mortality associated with the procedure. The increasing size of the unrelated donor registry, and the ability to safely transplant patients lacking an HLA matched donor with allografts from haploidentical donors and unrelated cord blood has led to an increase in the annual numbers of transplants performed for a variety of different malignant and non-malignant hematological disorders. Dr. Childs will review results of clinical trials evaluating transplant outcomes in patients receiving related, unrelated, haploidentical and cord blood transplants.
This session will:

- Update allogeneic transplantation for malignant and nonmalignant diseases: describing the state of the art of transplantation in 2023 and highlighting data showing the expanding role that haploidentical transplants are playing in this treatment modality
- Characterize the results of new FDA approved drugs to prevent and treat graft-versus-host disease and CMV
- Describe new strategies to prevent disease relapse after allogeneic transplantation

Key References:

1. Luznik L. et al JCO 2023:40:356-368
2. Avery R. et al Clin Infectious Diseases 2022: 75:4:690-701
3. Fuchs E. et al Blood 2021: 137:420-428
4. Hourigan C. et al JCO; 2020: 38;12
5. Cutler C. et al Blood 2021; 138 (22):2278-2289

Angela Fleishman, MD, PhD
Dr. Angela Fleischman is a physician-scientist investigating hematologic malignancies. She integrates her research with the clinical care of patients with these diseases. Her primary focus is the role of inflammation in Myeloproliferative Neoplasms. (Irvine, CA)

Abstract unavailable at the time of publication

Sandra G. Garofalo MS, APRN, C-NP
Nurse practitioner, Hematology Oncology of Indiana, a Division of American Oncology Network, (Indianapolis IN)

Sandra G. Garofalo has over 17 years of experience in the field of oncology. She completed her Bachelor of Science in nursing as well as her Master of Science at The Ohio State University. She started her nursing career in hematopoietic stem cell transplant at The Medical University of South Carolina. Since that time, she has had extensive experience in hematological and solid tumor malignancies as well as benign hematology at The James Cancer Center at The Ohio State University. She currently works as a nurse practitioner at Hematology Oncology of Indiana and St. Vincent's Hospital in Indianapolis.

Management of Long-Term Survivors of Hematologic Malignancies
Management of long-term survivors of hematological malignancies - Survivorship begins at diagnosis. Hematological disorders are diagnosed in great frequency in the US. Over 1.5 million people are estimated to be in treatment or remission for hematological disorders. There is an increased population of survivors over time, especially since the year 2000. Racial disparities exist among survivorship. Data and

interventions for equity will be presented.

NCCN standards of survivorship care include screening, monitoring for long-term effects, health maintenance and management, coordination of care as well as support and education and survivorship. Nursing survivorship care plans create improved outcomes. Monitoring and management of long-term physical as well as psychological effects of hematological malignancies as well as chemotherapy all need to be considered as part of survivorship care. First year survivorship is an opportune time to make changes and improve disease prevention and wellness habits. Psychosocial factors are an important issue that impacts patients and should continue to be assessed throughout survivorship. Continuing education, emotional and social support are essential aspects in continuing care of patients who are in remission or on maintenance therapy of hematological malignancies. Case studies will be presented, examined, and discussed to further illustrate appropriate survivorship care.

Morie Gertz, MD, MACP
Roland Seidler Jr. Professor, Art of Medicine, Chair Emeritus, Department of Internal Medicine, Mayo Clinic (Rochester, MN)

Dr. Gertz is a Master of the American College of Physicians. His undergraduate degree was awarded with highest distinction from Northwestern University graduating Phi Beta Kappa.

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Craig Kessler, MD
Professor of Medicine and Pathology and attending physician in the Division of Hematology-Oncology at Georgetown University Medical Center (Washington, DC)

He also serves as the Director of the Division of Coagulation in the Department of Laboratory Medicine and is the Director of the Therapeutic and Cellular Apheresis Unit. With a distinguished career beginning in 1973, Dr Kessler earned his medical degree from Tulane University School of Medicine in New Orleans, Louisiana. He remained in New Orleans to complete his medical internship and residency before moving to Baltimore, Maryland, in 1976 to assume a Fellowship in Special Hematology at Johns Hopkins Hospital.

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Rami S. Komrokji, MD
Dr. Komrokji is the Vice Chair of the Malignant Hematology Department and the head of the Leukemia and MDS Section at the Moffitt Cancer Center (Tampa, FL)

He is a senior Member of the Malignant Hematology and Experimental Therapeutics Program at the Moffitt Cancer Center, and Professor in Medicine & Oncologic Sciences at the College of Medicine, at the University of South Florida in Tampa, Florida. Dr Komrokji is world renowned expert in myeloid neoplasms where he led several clinical trials and lectured worldwide. His work paved the FDA approval for luspatercept in myelodysplastic syndromes and pending approval for Pacritinib in myelofibrosis.

Abstract unavailable at the time of publication

Richard Larson, MD
Professor of Medicine in Hematology/Oncology, Director of Hematologic Malignancies Clinical Research Program, the University of Chicago Comprehensive Cancer Center (Chicago, IL)

Dr. Richard Larson is Professor of Medicine in the Section of Hematology/Oncology and Director of the Hematologic Malignancies Clinical Research Program at the University of Chicago. He received his medical degree from the Stanford University School of Medicine in 1977, and completed his postdoctoral training in Internal Medicine, Hematology, and Medical Oncology at the University of Chicago. He has been a member of the faculty in the Section of Hematology/Oncology and the Comprehensive Cancer Center, University of Chicago since 1983.

Resistant and Recurrent Chronic Myeloid Leukemia
The 6 currently available BCR::ABL1 tyrosine kinase inhibitors (TKI) are remarkable effective and usually well-tolerated oral agents. Most newly diagnosed chronic phase patients rapidly achieve hematologic remissions within 4-6 weeks and early molecular responses (transcript level <10% at 3-6 months.) However, in some cases, primary resistance is observed, and others may show secondary resistance when patients have an initial response but quickly (usually within the first 6-24 months) have evidence of progression. The most common cause for primary resistance and recurrence is lack of adherence to the TKI prescription. Clearly, if patients do not take the drug, they do not get the benefit. Even the out-of-pocket co-pay for insured patients may be too much to afford. It is important to assess at each visit whether patients have been skipping doses. Another reason for not taking the TKI is cytopenias and physicians holding the therapy. Cytopenias are an on-target effect since most blood cells are derived from the Ph+ clone at diagnosis. As Ph+ cells clear from the marrow, it takes time for normal hematopoiesis to regenerate. Stopping the TKI only allows the malignant clone to re-expand. We almost never stop the TKI, but instead, we support patients with transfusions and hematopoietic growth factors (filgrastim, eltrombopag, or romiplostim) through the initial few weeks until their marrow function recovers. Although CML cells express GCSF receptors, as long as the TKI is continued, it is safe to use growth factor support. Some drugs and foods can interfere with the metabolism of the TKIs and reduce their activity. Side-effects are another reason for non-adherence. Fatigue is almost universal with TKI therapy although it often improves as anemia resolves. Every effort should be made to minimize nausea, diarrhea, and other GI toxicities.

Matthew Lunning DO, FACP
Associate Professor in the Division of Hematology/Oncology at the University of Nebraska Medical Center. Dr. Lunning also is Associate Vice Chair of Research for the Department of Internal Medicine, Medical Director of the Clinical Research Center (CRC), and Medical Director of Cellular Therapies. (Omaha, NE)
He received his medical degree from Des Moines University in 2006. Dr. Lunning completed his internal medicine residency at UNMC where he served as Chief Medical Resident. He completed his Hematology/Oncology fellowship and served as the Hematology Chief Fellow at Memorial Sloan-Kettering Cancer Center. Dr. Lunning returned to UNMC in 2013 and has been active in clinic research, research mentoring, education, and patient care. Dr. Lunning was the recipient of the Distinguish Scientist Award in 2019.

Abstract unavailable at the time of publication

Ruben Mesa, MD, FACP
Executive Director of the Mays Cancer Center, at UT Health San Antonio MD Anderson Cancer Center. (San Antonio, TX)

Having joined UT Health in 2017, Dr. Mesa began as Director of the cancer center. After earning degrees in nuclear engineering and physiology, with minors in radiation biophysics and bioengineering, from the University of Illinois at Urbana-Champaign, Dr. Mesa received his medical degree from the Mayo Graduate School at the Mayo Clinic College of Medicine in Rochester, Minnesota.

Diagnosis and Treatment of Myeloproliferative Neoplasms
The myeloproliferative neoplasms (MPNs) have a prevalence of around 350,000 in the USA and include the diagnoses of essential thrombocythemia (ET), polycythemia vera (PV), and myelofibrosis (MF). These clonal neoplasms share core set of acquired driver mutations in JAK2, calreticulin (CALR), and MPL which all lead to constitutive activation of the JAK-STAT pathway. Additionally, a range of somatic mutations may occur which impact disease phenotype as risk of progression (such as ASXL1, IDH1/2, EZH2, etc.). The burden of these illnesses include a predisposition to thrombosis or bleeding, a range of challenging symptoms (from spleen pain to hypermetabolic symptoms, pruritus, fatigue, and bone pain), splenomegaly, cytopenias, and potential progression to acute myeloid leukemia. Although the origin of these diseases is anchored in a clonal neoplastic process, inflammation potentially plays a role in the risk of thrombosis, the origin of many of the difficult symptoms, potential contribution to cytopenias, and the potential risk of progression from ET/PV to MF, or from MF to AML. A spectrum of cytokines have been found to be elevated in MPNs (especially in MF), with elevation of certain ones negatively impacting prognosis including IL-8, IL-2R, IL-12, and IL-15. Therapy of MPNs now includes non-specific cytoreduction (i.e., hydroxyurea for ET-PV), long acting interferons (i.e., pegylated interferon alpha-2b for PV), and JAK inhibition with ruxolitinib (inhibits JAK1 and JAK2), fedratinib (JAK2 and FLT3), pacritinib (inhibits JAK2, FLT3, IRAK1, and ACVR1), and momelotinib (inhibits JAK1, JAK2, ACVR1). The JAK inhibitors have made a significant impact on decreasing the burden MPN patients face by decreasing splenomegaly (and its associated symptom burden), by decreasing MPN associated symptoms, and by improving survival. The mechanism of improved survival is not fully understood but may include a decrease in marrow inflammation and perhaps decreasing the mutagenic pressure that leads to additional somatic mutations such as ASXL1 that lead to AML. Hepcidin associated with inflammation is dually being investigated as means to decrease erythrocytosis in PV with hepcidin mimetics (i.e., rusferatide), and to improve MF associated anemia by inhibiting hepcidin (momelotinib or pacritinib by ACVR1 inhibition). Inflammation as both a driver of disease burden and progression, as well as a viable therapeutic target remains an important focus of investigation and interventional trials.

Joseph Mikhael, MD, MEd, FRCPC, FACP
Dr. Mikhael is a Professor in the Applied Cancer Research and Drug Discovery Division at the Translational Genomics Research Institute (TGen), an affiliate of City of Hope Cancer Center. He is also the Chief Medical Officer of the International Myeloma Foundation (IMF) and Director of Myeloma research at the HonorHealth Research Institute. (Montreal, Quebec)

Dr. Mikhael specializes clinically in plasma cell disorders, namely multiple myeloma, amyloidosis, and Waldenström macroglobulinemia. He is the PI of many clinical trials, primarily in relapsed multiple myeloma, and his other clinical research interests include pharmaco-economics, communication skills, and media relations.

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2023 FACULTY AND ABSTRACTS CONTINUED

Kristi Orbaugh, MSN, RNP, AOCN
Kristi's entire career has been in the oncology field. She received her undergraduate degree from Purdue University and her master's degree from Indiana University Purdue University of Indianapolis. She works at Community Hospital Cancer Center North which is an affiliate of MD Anderson as a nurse practitioner. She has published several oncology related articles. She has presented locally, regionally, nationally, and internationally. Kristi is passionate about oncology and enjoys presenting and providing oncology education on regional, national, and international level. (Indianapolis, IN)

Recognizing Toxicities of Oral Oncolytics in the Management of Hematologic Malignancies
Combination chemotherapy regimens have added to the complexity of cancer treatment. When oral oncolytic drugs are used, they add another layer of complexity due to their potential toxicities and the need for patient adherence. Oral chemotherapy drugs have the potential to cause toxicities that will need to be assessed regularly. In this presentation, the focus will be on discussing some of the toxicities that are seen with regimens that are frequently used to treat hematologic malignancies.

It is vital that oncology nurses recognize and regularly assess for potential toxicities caused by oral chemotherapy. Differentiating between drug toxicity and symptoms from the disease will need to be evaluated as well. Nurses will also need to educate patients on potential side effects and have a plan for managing any toxicities. Education is imperative in helping patients understand the proper way to take their medication, and the importance of adhering to the medication regimens. Finally, financial toxicity will be discussed briefly.

Tycel Phillips, MD
Associate Professor, Division of Lymphoma, Department of Hematology and Hematopoietic Cell Transplantation, City of Hope Comprehensive Cancer Center (Duarte, CA)

Dr. Phillips earned his medical degree from Rush University, followed by a residency in internal medicine at the John H. Stroger Jr. Hospital of Cook County in Chicago. His fellowship training in oncology/hematology took place at University Hospitals in Cleveland. Before joining City of Hope, he was a clinical associate professor at the University of Michigan, where he was appointed the Maria Reinhardt DeCesare Research Professor of Blood Cancers and Bone Marrow Transplantation.

Updates in Lymphoma
Over the last several years significant changes have occurred in the lymphoma treatment landscape. For diffuse large B cell lymphoma (DLBCL), R-CHOP has remained the standard of care since the early 2000s. Since that time, we have continued to attempt to make improvements to this regimen without much success. The POLARIX study which compared R-CHOP to R-CHP + polatuzumab demonstrated a PFS benefit with the addition of polatuzumab to frontline therapy but to date has not demonstrated a survival benefit. Nonetheless, a recent NCCN updated has listed the regimen as category 1 treatment for newly diagnosed patients. For follicular lymphoma (FL) the greatest need continues to be in patients who relapse within 24 months of initial therapy. Several new agents such as the CD20/CD3 bispecific antibodies have been shown promise in these patients. These agents look likely to impact both relapsed/refractory (RR) FL and DLBCL. This drug class offers comparable efficacy to CAR-T with less frequent and severe adverse events of CRS and ICANS. Mosunetuzumab was recently approved for R/R FL, and we expect approval of epcoritamab and glofitamab for R/R DLBCL later this year. For MCL, early results of the TRIANGLE study, hint to the end for autologous stem cell transplant in frontline therapy. The 2nd generation covalent BTKI, zanubrutinib, was reported in the ALPINE study to have greater benefit in CLL patients compared to ibrutinib. In the end we are in the midst of several exciting changes that appear likely to improve outcomes for patients diagnosed with lymphoma.

David Reeves, PharmD, BCOP
Associate Professor of Pharmacy Practice, College of Pharmacy and Health Sciences, Butler University, Clinical Pharmacy Specialist in Hematology/Oncology, Franciscan Physician Network Oncology/Hematology Specialist (Indianapolis, IN)

David is an associate professor of pharmacy practice for the College of Pharmacy and Health Sciences at Butler University and clinical pharmacy specialist in hematology/oncology at Franciscan Physician Network Oncology/Hematology Specialists in Indianapolis, IN.

Understanding and Managing Immune Effector Toxicities in Hematologic Toxicities
The therapeutic use of immune system manipulation to treatment hematologic malignancies continues to expand with the use of chimeric antigen receptor (CAR) T-cell therapies, and bispecific T-cell engagers (BiTEs). In addition to the immune related destruction of malignant cells, immune effector cells can also produce significant toxicity. In fact, upwards of 90% or more patients, depending on the definitions utilized, experience immune effector toxicity with CAR T-cell therapies. Toxicities associated with immune effector cells include cytokine release syndrome and neurotoxicity. Established therapy to reverse the hyperinflammatory state and decrease effects of cytokines include use of an IL-6 receptor antibody (tocilizumab) and steroids. Judicious use of immune suppression is based on grade of toxicity as defined by the American Society for Transplantation and Cellular Therapy consensus grading. The majority of patients

respond to therapy; however, work continues to optimize management of this potentially fatal toxicity. Despite the concern that steroids may impact CAR T-cell expansion and persistence, a study of axicabtagene ciloleucel investigated the use of prophylactic steroids and demonstrated a low risk for grade 3 or higher toxicity without compromising efficacy. Likewise, anakinra, an IL-1 receptor antagonist, has been investigated in both the therapeutic and prophylactic settings with promising results. Other agents with emerging data include JAK pathway inhibitors (ruxolitinib, itacitinib) and a granulocyte-macrophage-colony-stimulating factor directed monoclonal antibody (lenzilumab). To support the increasing number of patients receiving therapies associated with immune effector cell toxicities, guideline driven management along with novel therapeutic and prophylactic approaches are necessary to decrease the impact of toxicity.

Gilles Salles, MD, PhD
Chief of the Lymphoma Service at the Memorial Sloan Kettering Cancer Center (New York, NY)

He has previously held a position of professor of hematology and medicine at the University of Lyon, and head of the Department of Hematology at the Hospices Civils de Lyon, Centre Hospitalier Lyon-Sud, in Pierre-Bénite, France. Professor Salles obtained his doctoral degree in differentiation, genetics, and immunology, as well as his medical degree, from Université Claude Bernard Lyon-1. He completed further training in Oncology and also served as a researcher at the Dana-Farber Cancer Institute of Harvard Medical School in Boston, Massachusetts.

Abstract unavailable at the time of publication

Charles Schiffer, MD
Emeritus Professor of Oncology and previously the Joseph Dresner Chair for Hematologic Malignancies and Director of the Leukemia/Lymphoma Multidisciplinary Program at Wayne State University School of Medicine and the Karmanos Cancer Institute. (Detroit, MI)

Dr. Schiffer has authored and co-authored more than 350 articles and 80 book chapters on topics concerning the treatment of leukemia in adults, platelet transfusion, and granulocyte transfusion therapy, among others.

Abstract unavailable at the time of publication

Wendy Stock, MD, MA
Professor of Leukemia Research at the University of Chicago. (Chicago, IL)

Dr. Stock is the Anjuli Seth Nayak Professor of Leukemia Research at the University of Chicago. She is an expert in clinical and correlative laboratory research involving acute leukemias. Her focus has been to design biologically risk-adapted clinical trials for patients with acute leukemias, leading national trials for treatment of acute lymphoblastic leukemia (ALL) that have helped to change the standard of care for young adults with this disease. Dr. Stock has also established a young adult leukemia clinic at the University of Chicago which she runs jointly with her pediatric colleagues, and which is committed to providing innovative research trials and clinical care to this patient population. She is currently the co-leader for Clinical and Experimental Therapeutics in the University of Chicago Comprehensive Cancer Center.

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Richard Stone, MD
Chief of Staff and Director of Translational Research, Adult Leukemia Program, Professor of Medicine, Harvard Medical School, Dana-Farber Cancer Institute (Boston, MA)

Richard Stone, MD, is the Chief of Staff at Dana-Farber Cancer Institute (DFCI). He is also Director of Translational Research for the Leukemia Division of Medical Oncology at DFCI, and Professor of Medicine at Harvard Medical School. He is nationally recognized for his translational and clinical research concerning blood and bone marrow malignancies including acute leukemia, myeloproliferative disorders, and myelodysplastic syndrome.

Apollo and The Indianapolis Oracle: Prognostication and Treatment of Myelodysplastic Syndromes
The myelodysplastic syndromes (MDS) represent a group of clonal marrow stem cell disorders usually characterized by a hypercellular marrow with morphologic dysplasia in at least one hematopoietic lineage with peripheral cytopenias. Mutations in genes encoding splicing and transcription factors are common, some of which may precede a formal diagnosis of MDS in the form of clonal hematopoiesis of indeterminate potential (CHIP) or clonal cytopenias of uncertain significance (CCUS). Agents which may reduce the risk of transition from CHIP/CCUS to actual MDS, especially in those at high risk are in development. The last year has brought one new (ICC, International Consensus Classification) and revamped WHO nosologic algorithms form the definition of MDS; the ICC has proposed a new category in which those with 10-19% marrow blasts should be considered as MDS/AML. The recently introduced Molecular International Prognostic Scoring System (IPSS-M) algorithm (see

https://mds-risk-model.com/) which uses clinical features and presence or absence of mutations in 17 genes provides accurate prognostication. MDS therapy can be summarized as risk adapted. Lower risk patients are treated with supportive care including transfusions, hematopoietic growth factors (especially erythroid stimulating agents, or luspatercept (an anti-cytokine drug active in those with ringed sideroblasts). A three-day decitabine regimen may be used in such patients who are refractory to supportive care. Hypomethylating agents (HMA; IV decitabine, IV or SC azacytidine, or oral decitabine/cedazuridne) are the mainstay of therapy for patients with higher risk MDS, but improvements in such single agent therapy are sorely needed, especially for the subtype of patients with TP53 mutant disease.

Martin Tallman, MD
Most recently, Professor of Medicine at Weill Cornell Medical College in New York, USA, and former Chief of Leukemia Service at Memorial Sloan Kettering Cancer Center. Dr. Tallman completed his fellowship in hematology/oncology at the University of Washington and the Fred Hutchinson Cancer Research Center in Seattle, Washington, USA. (New York, NY)

His research interests include clinical investigation in acute myeloid leukemia, acute lymphocytic leukemia, acute promyelocytic leukemia, and hairy cell leukemia.

Improving Outcomes with Current Therapies in Acute Myeloid Leukemia and Acute Promyelocytic Leukemia: What We Recommend in 2023
Recent progress in acute myeloid leukemia (AML) includes insights into genetic pathogenesis, recognition of inherited familial predisposition syndromes, development of targeted therapies, expanded availability and advances in transplantation, new approaches to older adults and incorporation of minimal (measurable) residual disease into clinical decisions. Patients with recurrent genetic abnormalities now are classified as AML if they have >/=10% blasts in bone marrow or blood including NPM1 and bZIP CEBPα. Since 2017 there have been 10 new agents approved for AML. Among them Midostaurin, CPX-351, Gemtuzumab ozogamicin (GO) and Venetoclax (Ven) have changed the standard of care. The combination of Ven and hypomethylating agents (HMA) is a particularly important advance and provides effective well-tolerated treatment for older adults and those unsuitable for intensive chemotherapy. It may well replace conventional induction chemotherapy for patients with adverse cytogenetics among older and potentially even younger patients. HMA/Ven serves as a backbone for additional combinations (triplets) including FLT3 inhibitors and other novel agents. Among most promising are Magrolimab (anti-CD47 antibody) and SNDX-5613 (menin inhibitor) the latter of which appears promising in patients with MLL gene rearrangements and those with NPM1 mutations. Acute promyelocytic leukemia is highly curable with all-trans retinoic acid (ATRA) (administered at first suspicion of disease) and arsenic trioxide (ATO). Seventy-five percent of patients present with low-risk disease among whom ATRA and ATO without chemotherapy or maintenance cures 98% if patients survive induction since no primary resistance exists. Those with high-risk disease require addition of chemotherapy, an anthracycline or GO, and in some protocols, maintenance. For high-risk disease, one can consider 12-24 hours of ATRA first to stabilize the coagulopathy. Studies with oral ATO will be available soon.

Ayalew Tefferi, MD
Barbara Woodward Lips II Professor of Medicine at the Mayo Clinic (Rochester, MN)

Dr. Tefferi's research interest is primarily focused on myeloid neoplasms including acute myeloid leukemia and chronic myeloid neoplasms. His web of science core collection publications, as of 6/3/2021, number over 1500 with an H-index of 120. He has participated in hundreds of invited lectureships including service as core faculty for GW, MDACC and Harvard annual board review courses.

Primary myelofibrosis: 2023 update
Disease overview: Primary myelofibrosis (PMF) is a myeloproliferative neoplasm (MPN) characterized by stem cell-derived clonal myeloproliferation that is often but not always accompanied by JAK2, CALR, or MPL mutations; additional features include bone marrow reticulin/collagen fibrosis, aberrant inflammatory cytokine expression, anemia, hepatosplenomegaly, extramedullary hematopoiesis, constitutional symptoms, cachexia, risk of leukemic progression, and shortened survival.

Mutations: SRSF2, ASXL1 and U2AF1-Q157 mutations predict inferior survival while type 1/like CALR mutation is associated with superior survival.
Karyotype: Very high-risk abnormalities include -7, inv (3), i(17q), +21, +19, 12p- and 11q-. Favorable risk abnormalities include normal karyotype or isolated +9, 13q-, 20q-, 1q abnormalities and loss of Y chromosome.

Risk stratification: Contemporary prognostic systems include GIPSS (genetically inspired prognostic scoring system) and MIPSS70+ version 2.0 (MIPSSv2; mutation- and karyotype-enhanced international prognostic scoring system). GIPSS is based exclusively on mutations and karyotype; MIPSSv2 includes, in addition, clinical risk factors.
Risk-adapted therapy: Observation alone is advised for MIPSSv2 "low" and "very low" risk disease (estimated 10-year survival 56%-92%); allogeneic hematopoietic stem cell transplant (AHSCT) is the preferred treatment of choice for "very high" and "high" risk disease (estimated 10-year survival 0-13%), as well as in select patients with intermediate-risk disease (estimated 10-year survival 30%). Drug therapy in MF is currently palliative and targets anemia, splenomegaly, and constitutional symptoms.

JAK2 inhibitors: Ruxolitinib, fedratinib and pacritinib are FDA approved and respectfully utilized in patients failing treatment with hydroxyurea, ruxolitinib, or with platelet count <50 x 10(9)/L. Momelotinib is another JAK2 inhibitor that is poised for approval sometime in 2023 and has shown erythropoietic benefit, in addition to effecting spleen and symptom responses.
New directions: New agents, alone or in combination with ruxolitinib, are currently under clinical trial investigation and include a monoclonal antibody strategy that targets CALR mutations.

Steven P. Treon, MD, MA, PHD, FRCP, FACP
Steve Treon is the Director of the Bing Center for Waldenstrom's Macroglobulinemia (WM) at the Dana Farber Cancer Institute (DFCI), a Professor of Medicine at Harvard Medical School, and Chair of the WM Clinical Trials Group (Boston, MA)

His laboratory first identified highly recurring activating mutations in MYD88 and CXCR4 using whole genome sequencing. Professor Treon's laboratory also identified that Bruton's tyrosine kinase (BTK) was a downstream target of mutated MYD88, and enabled a clinical trial with the BTK inhibitor ibrutinib that resulted in the first-ever approval of a drug by the U.S. FDA and the European Medicines Agency for WM. Professor Treon also made major contributions to the investigation and advancement of many novel agents used to treat WM including monoclonal antibodies, nucleoside analogues, bendamustine, proteasome inhibitors, and BTK inhibitors.

Beyond Hyperviscosity: 80 Years and Counting, Treatment of Waldenstrom's Macroglobulinemia

Waldenstrom's macroglobulinemia (WM) is an indolent B cell lymphoma that is classified as an IgM producing lymphoplasmacytic lymphoma under the WHO classification system. Morbidity related to WM includes tumor infiltration of the bone marrow and extramedullary sites, as well as paraprotein production that can cause symptomatic hyperviscosity, demyelinating neuropathy, cryoglobulinemia, or cold agglutinemia. Approximately 95-97% of WM patients harbor activating mutations in MYD88, most typically L265P variant, whilst up to 40% can carry somatic mutations in CXCR4 that include both nonsense and frameshift variants1. MYD88 mutations trigger downstream NFKB pro-survival signaling mediated by BTK, whilst CXCR4 mutations trigger AKT and ERK that impact drug sensitivity particularly to BTK-inhibitors1,2. The above findings have triggered development of BTK-inhibitors including both covalent and non-covalent agents. Ibrutinib alone and in combination with rituximab is highly active, producing responses in over 90% of patients, and long-term disease control. However, underlying MYD88 and CXCR4 mutation status can impact time to major response, response depth, and/or progression-free survival.3,4 Zanubrutinib has shown overall responses in 90% of WM patients, and in a randomized study (ASPEN trial) exhibited deeper responses (VGPR or better) in comparison to ibrutinib5. Less patients on zanubrutinib had atrial fibrillation on the ASPEN study; conversely fewer patients on ibrutinib experienced Grade 3 or higher neutropenia highlighting important differences between BTK-inhibitors. Genomic differences were also apparent in the ASPEN study. Patients with CXCR4 mutations exhibited fewer VGPR or better responses on both arms. However, patients with CXCR4 mutations including those with nonsense CXCR4 variants exhibited better progression-free survival on zanubrutinib, while significant activity was also observed for MYD88 wild-type patients who received zanubrutinib in a dedicated single arm cohort on ASPEN. Acalabrutinib is also active in WM, with 90% overall response activity in both treatment naïve and previously treated WM patients. Atrial fibrillation was seen in 12% of previously treated WM patients, similar to the incidence observed with single agent ibrutinib.6 Compliance, necessity for deep IGM reduction, morbidity, presence or predisposition to adverse events including atrial fibrillation and cytopenias, as well as underlying genomic findings are key considerations to the choice of a BTK-inhibitor for WM therapy. Dose reduction, and switchover to an alternate covalent BTK-inhibitor represent approaches for managing intolerance.7,8 Novel non-covalent BTK-inhibitors, and venetoclax represent novel therapeutics for acquired resistance to covalent BTK-inhibitors.9,10 Targeting CXCR4 in CXCR4 mutated WM patients is under evaluation with encouraging findings.11

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Saad Z. Usmani, MD MBA FACP
Chief of Myeloma Service Member, Memorial Sloan Kettering Cancer Center, Attending Physician, Myeloma, Cellular Therapy and Adult BMT Services (New York, NY)

Dr. Saad Zafar Usmani received his medical education at Allama Iqbal Medical College in Lahore, Pakistan. He completed a residency in internal medicine at Sinai-Grace Hospital/Wayne State University in Detroit, Michigan and a fellowship in hematology and oncology at the University of Connecticut Health Center in Farmington, Connecticut. He then joined the Myeloma Institute for Research & Therapy, University of Arkansas for Medical Sciences in Little Rock, AR in 2010 as the Director of Developmental Therapeutics and Assistant Professor of Medicine. He was recruited to the Levine Cancer Institute/Atrium Health in 2013 as the inaugural Division Chief of Plasma Cell Disorders and Director of Clinical Research for Hematologic Malignancies where he built an internationally renowned myeloma program. He now serves as the Chief of Myeloma Service at MSKCC.

Abstract unavailable at the time of publication

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Abstract unavailable at the time of publication

Michael Wiemann, MD, FACP
Vice President, Indy Hematology Education, Inc., President of Providence Hospital, Executive Vice President West Region, St. John Providence Health System (Warren, MI)

Dr. Wiemann is the President of the Ascension Medical Group, Michigan, and Clinical Professor of Medicine at Michigan State University College of Human Medicine. Dr. Wiemann is a medical oncologist and Co-Founder of the Indy Hematology Review. While in Indianapolis, he held several leadership positions at St. Vincent Hospital and Health Center, including Medical Director of Oncology, Chief Medical Officer, and Interim President.

Abstract unavailable at the time of publication

Jennifer Woyack, MD
Professor in the division of Hematology, the section chair of Chronic Lymphocytic Leukemia (CLL), and a physician scientist focused on translational research in CLL at the Ohio State University. Her laboratory interests include experimental therapeutics in CLL with a focus on signaling pathways and kinase inhibition. She has extensive experience studying BTK inhibitors, resistance mechanisms associated with irreversible BTK inhibitors, and strategies to overcome resistance. (Columbus, OH)

Therapeutic Options in CLL in 2023: Choosing Wisely: Initial Therapy for CLL
The current treatment of CLL involves targeted therapies that exploit specific vulnerabilities in CLL cells. These include either inhibitors of Bruton's Tyrosine Kinase (BTKi) or the BCL2 inhibitor venetoclax plus the anti-CD20 antibody obinutuzumab (VO). The optimal sequence of these therapies remains unclear, however, accumulating data suggests that either sequence can be effective. Different BTKis approved for CLL include ibrutinib, acalabrutinib, and zanubrutinib, all covalent inhibitors. Ibrutinib is the first-in-class molecule and has the longest follow-up, with a median PFS of over 6.5 years in the pivotal trial 1. Two second-generation inhibitors, acalabrutinib and zanubrutinib have since been approved based upon phase 3 trials showing similar efficacy, albeit shorter follow-up. 2 3 Based upon head-to-head studies showing lower cardiovascular adverse events with either acalabrutinib 4 or zanubrutinib, 5 these two are preferred per NCCN guidelines. VO demonstrated a PFS rate of 62.6 percent at 5 years after

randomization with a 1 year fixed duration treatment. 6 PFS rates with VO may depend more heavily on genomic features than BTKi do, however, even high risk patients may have long remissions. In 2023, we may also have the option of combination BTKi plus venetoclax, although the question remains of whether these have an efficacy advantage over VO. For most patients, the choice between BTKi and VO is based upon safety profiles and desire for a finite treatment duration. Current and future studies will help to define the optimal therapy for individual patients, but in the absence of these data, patients still have multiple effective and safe options for treatment.

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An Interview with Ruemu Birhiray, MD
Achieving Tomorrow's Outcomes Through Education Today TM: 20 Years of the Indy Hematology Review®

Written by Nicola Donelan

Twenty years is a remarkable milestone and certainly meant to be celebrated. We may not be celebrating a wedding anniversary, but the commitment that is involved in organizing the annual Indy Hematology Review meeting is comparable to a solid and enduring long-term relationship. Twenty years of providing education for physicians, nurse practitioners, nurses, and other healthcare professionals. Twenty years of networking, organizing, funding, initiatives, progress and building relationships.

According to google, emerald is the gemstone of the 20th anniversary in marriage. Emerald is a stone of inspiration and infinite patience. Focusing intention and raising consciousness, it brings about positive action. These precious green gems impart mental clarity, strengthens memory, inspires a deep inner knowing and broadens vision. It is a wisdom stone, promoting discernment and truth, and aiding eloquent expression. Emerald is extremely beneficial to mutual understanding within a group of people and stimulating cooperation. Everyone should be wearing emeralds this year, such a pity that the price of these precious stones will prohibit that becoming reality, but an emerald green tie, shirt or dress would be possible.

Dr. Ruemu Birhiray recalls that in 2003 the emergence of monoclonal antibodies for lymphoma, leukemia and of proteasome inhibitors for myeloma were the exciting developments in hematology. Now, two decades later the list of therapies is much longer and according to Dr. Birhiray this makes things more complicated, but also more exciting.

"20 years ago, Indy Hematology Review® was created, today we celebrate education, learning and our great faculty," Dr. Birhiray proudly announced. Somewhere during the two decades of Indy Hematology Review ® the trademarked slogan of **"Achieving Tomorrow's Outcomes Through Education Today, TM"** came into being.

The need for an organization like Indy Hematology in Indiana in undeniable. Thousands of Americans are diagnosed with some form of blood cancer every year and raising awareness and providing education regarding hematology and oncology diseases and disorders is vital. Most patients with hematologic malignancies in the US are treated at community oncology practices, yet the majority of cutting-edge available therapies are delivered at academic centers where certain demographics of patients are served more than others. This year the Indy Hematology Review® will start a new initiative that addresses this issue with a focus on delivering cellular therapies including bi-specific antibodies, CAR-T therapies and other immunotherapies directed towards T-cells or malignant cells to the community.

This organization will be called the CONCERT NETWORK (Community **ON**cology **CE**llula**R T**herapy Network) and consist of community providers who are interested in establishing the infrastructure for cellular therapies and delivering such services to their patients. The inaugural meeting of the CONCERT NETWORK will be held on March 17, 2023 at The Westin Indianapolis, Indiana and will be focused on bi-specific antibody therapies.

"We truly believe in our slogan of Achieving Tomorrow's Outcomes Through Education Today TM and are very excited to celebrate our 20th year and to continue providing this service to our local community," said Dr. Birhiray.

Improving outcome for patients is at the core of what the Indy Hematology Review ® is about, and the ever-evolving landscape of therapeutic choices makes it challenging for healthcare professionals to stay on top of every development on their own. There is strength in numbers, in community, and learning from each other. Onwards and upward to the next decade!

T. HOWARD LEE AWARD RECIPIENTS

T. Howard Lee, MD, founder and President Emeritus, Hematology Oncology of Indiana, PC (Indianapolis, IN)

The following respected individuals have been presenters and recipients at the T. Howard Lee Keynote Lecture:

2003: Professor Bertrand Coiffier, MD
Bertrand Coiffier is Professor of Hematology at the Department of Hematology, Hospices Civils de Lyon and the University Claude Bernard, Lyon, France, Chairman, GELA

2004: Kanti Rai, MD
Past President of American Society of Hematology, ASH, Chief, Division of Hematology/Oncology, Long Island Jewish Medical Center, Professor of Medicine, Albert Einstein College of Medicine

2005: Claire Dearden, MBBS
Dr Claire Dearden is Consultant Hematologist and Head of the Chronic Lymphocytic Leukemia (CLL) Unit at The Royal Marsden and The Institute of Cancer Research, and Medical Director of the South West London Cancer Network.

2006: Sandra Horning, MD
Professor of Oncology, Sanford University, Past President of The American Society of Oncology, ASCO

2007: Lewis R. Silverman, MD
Director, Myelodysplastic Syndrome and Myeloproliferative Disease Program, Mount Sinai School of Medicine, New York, NY

2008: Neal Young, MD
Chief of the Hematology Branch of the National Heart, Lung and Blood Institute, National Institute of Health, Bethesda, MD

2009: Professor Michael Pfreundschuh, MD
Professor and Director of Medical Oncology, Department of Internal Medicine, Saarland University, and Chairman, German Lymphoma Group

2010: James Armitage, MD
Past President of ASCO, Joe Shapiro Professor of Medicine, and Past Dean, University of Nebraska Medical School, Omaha, NE

2011: Michael Keating, MBBS
Professor of Medicine and Internist, Department of Leukemia, Division of Cancer Medicine, The University of Texas MD Anderson Cancer Center, Houston, TX

2012: Kenneth Anderson, MD
Kraft Family Professor of Medicine, Department of Medicine, Harvard Medical School, Medical Director, Kraft Family Blood Center, Dana-Farber Cancer Institute, Boston, MA

2013: Susan O'Brien, MD
Ashbel Smith Professor and Chief of the Section of Acute Lymphocytic Leukemia, Department of Leukemia at the University of Texas MD Anderson Cancer Center

2014: Ross Levine, MD
Associate Attending Physician at Memorial Sloan-Kettering Cancer Center, Associate Professor of Medicine at Weill Cornell Medical College, New York, NY

2015: Stephen Ansell, MD, PhD
Professor of Medicine, Mayo Clinic Department of Hematology at the Mayo Clinic, MN

2016: David Porter, MD
Abramson Cancer Center, University of Pennsylvania Health System, Jodi Fisher Horowitz Professor of Leukemia Care Excellence Director, Blood and Marrow Transplantation, Philadelphia, PA

2017: Bruce Cheson, MD
Deputy Chief, Division of Hematology/Oncology in the Department of Medicine, Head of Hematology and Professor of Medicine, Lombardi Comprehensive Cancer Center, Georgetown University Hospital, Washington, DC

2018: Thomas Kipps, MD, PhD
Deputy Director of Research, Moores UCSD Cancer Center; Professor of Medicine UC San Diego, School of Medicine, San Diego, CA

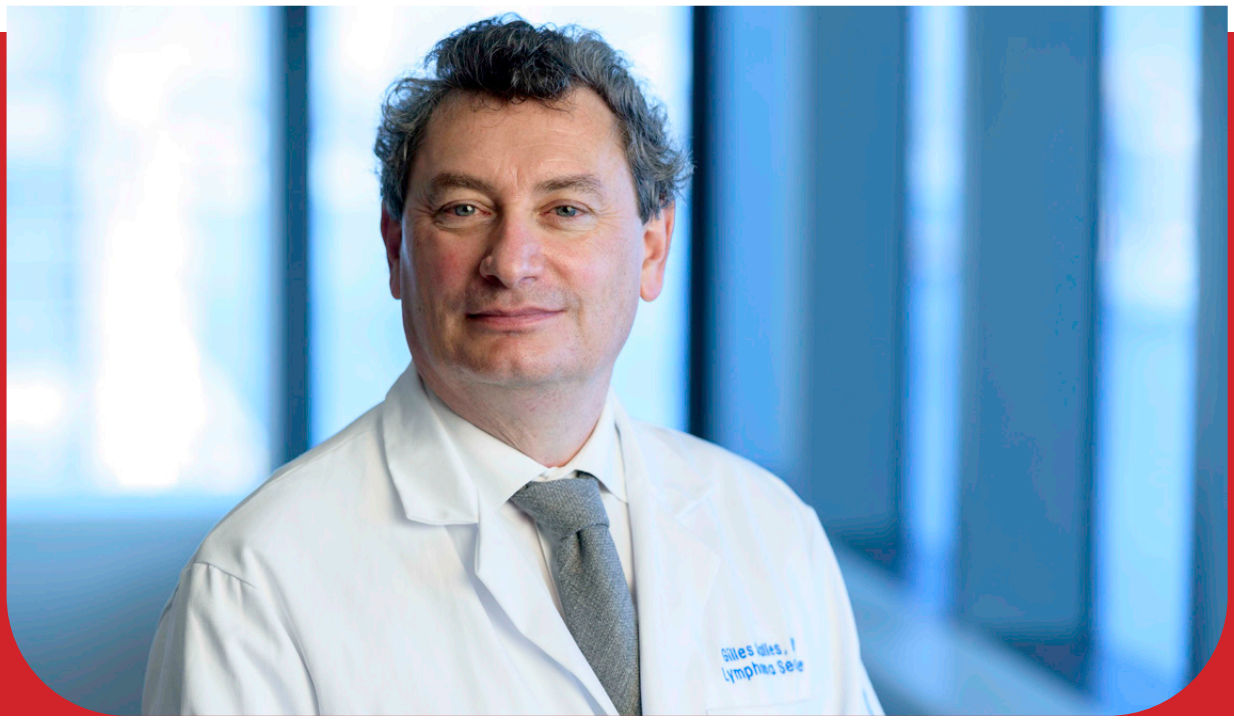
2019: Pier Luigi Zinzani, MD, PhD
Professor of Hematology, Head of Lymphoma Group, Institute of Hematology, "L. e A. Seràgnoli", University of Bologna, Bologna, Italy

2020: Edward Stadtmauer, MD
Professor of Medicine and Section Chief of the Hematologic Malignancies in the Division of Hematology-Oncology at the Hospital of the University of Pennsylvania, Philadelphia, PA

2021: Ranjana Advani, MD
Saul A. Rosenberg Professor of Lymphoma at Stanford University School of Medicine and Physician Leader of the Lymphoma Clinical Care Program, Stanford, CA

2022: Sonali Smith, MD, FASCO
Elwood V. Jensen Professor of Medicine, Section Chief of Hematology/Oncology, Co-Leader of the Cancer Service Line, and Co-Director of the Lymphoma Program at the University of Chicago in the Department of Medicine, Chicago, IL

2023: Dr. Gilles Salles, MD, PhD
Chief of the Lymphoma Service at the Memorial Sloan Kettering Cancer Center, New York, NY



AN INTERVIEW WITH 2023 T. HOWARD LEE PRESENTER: GILLES SALLES, MD, PHD ADVANCING LYMPHOMA THERAPIES

Written by Nicola Donelan

"Cancer has to be fought and defeated, and that will require mobilizing your brain and your efforts," says Professor Salles. Around 35 years ago he became fascinated with oncology as a field because discoveries were being made rapidly, and there were opportunities to bring these discoveries to patients. Early on in his career, Gilles had the opportunity to spend 2 years in the United States, in Boston, at the Dana-Farber Cancer Institute at Harvard medical school. This reinforced his belief that connecting and collaborating with many people on an international stage was going be the direction his career would take rather than being confined to one city or hospital in his home country of France. Currently, he is back in the US at Memorial Sloan Kettering Cancer Center in New York city where he is the acting Chief of the Lymphoma Service in the Department of Medicine. He shared his insights with us on being a practicing clinician and active researcher in hematology oncology, as well as the progress being made in treating follicular lymphoma and other B cell malignancies.

A REWARDING LEARNING EXPERIENCE IN A RAPIDLY ADVANCING FIELD

"As an oncologist, you must build a relationship of trust with the patient, and what is on the table is basically life and death, and you cannot play with that," explains Salles.

Building a sincere relationship, being transparent about the entire journey when a patient has cancer is critical. There are times when physicians share good news, and we are fortunate in hematology to often share good news, but sometimes we share bad news, but that brings us to a human quality of the exchange that I will say it's unique as a human being.

"There is probably no clinic day where I don't learn from one of my patients or their family about, the reactions, the strengths and how admirable they are in their own journey," says Salles.

Professor Salles outlined that the hematology field that has been completely transformed over the last 20-30 years. First, with the advent of small monoclonal antibodies being approved for treatment of

lymphoma, then the first targeted therapies for hematological malignancy in CML. Following on these therapies, a few that came to the field of lymphoid malignancy like CAR-T cellular therapy, bispecific and trispecific antibodies. In terms of clinical research, we are trying to bring to patients the new tools that can control and cure the disease, and figuring out optimal combinations and sequencing of different therapies is key explained Salles.

"We are facing the development of tools that really improve the number of patients cured, or the life expectancy of those that are facing chronic diseases and being modestly but still actively involved in this progress, is obviously something that makes you happy to go to work every morning," says Salles.

BROADENING OUR UNDERSTANDING OF FOLLICULAR LYMPHOMA

A major focus of Professor Salles' research is on follicular lymphoma, a frequent subtype of lymphoma which has many challenges because it remains an incurable disease. Therapies are allowing patients with follicular lymphoma to have prolonged the life expectancy by decades, and we are able to control that disease with less toxicity than before, and the hope is to be able to cure more patient with this disease in the near future predicts Salles.

"This interplay between the genetics, the mutations in the core of the cell program, what we call epigenetic mutation, and that influence in cell-cell interaction is something quite fascinating to try to understand," describes Salles. Understanding that the mutations that are present in the tumor cells completely remodel the relationship of this tumor cell with the immune environment give us the opportunity to reactivate the patient's immunity and Salles hopes this will lead to ways to control or to cure this disease.

CAR-T CELLS AS A STANDARD OF CARE FOR B CELL LYMPHOMAS

Cell therapy in the form of CAR-T cells are becoming the standard of care, or at least a part of the standard of care for the vast majority of patient with B cell lymphoma. Virtually all patients with B cell lymphoma can use CAR-T since there is no real age limit for this kind of therapy.

"We are infusing patients with a few 100 of millions of cells, that is something very small that can fit at the bottom of a test tube, and these cells will develop and cure tumors, that are 1-2 kg in size in the patient which is both impressive and amazing," highlights Salles.
He went on to say that some hematology colleagues who did the research and promoted this treatment to be brought to the patient, may have foreseen their incredible potential, but now as clinicians, we are able to really see how transforming it is for the lives of our patients. According to Professor Salles, it currently takes one month for an individualized CAR-T therapy to be manufactured ex vivo, but the field is advancing rapidly, and he predicts this manufacturing time will be reduced to two weeks or even 10 days in the near future. Additionally, there is the possibility in the future to develop cellular therapies in vivo.

"We have learned with the COVID pandemic story and the vaccines, that we are also able to bring genetic materials in the patient and modify cells in vivo, maybe that will happen for cancer therapy also, maybe it's science fiction, but I don't think it is," says Salles.

Professor Salles is very much looking forward to attending and speaking at the 20th Indy Hematology Review. He shared a small joke about the fact that this will be his first time at the Review and yet they have already invited him to come again next year.

"I'm very honored to have been invited and glad to be part of this event, but you should probably hear my talk before you invite me for next year," mused Salles.

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An Interview with AON Leader Stephen “Fred” Divers, MD

Stephen “Fred” Divers, MD, is a Board-certified medical oncologist at Genesis Cancer and Blood Institute, a partner practice of American Oncology Network, LLC (AON), in Hot Springs, Arkansas. He serves as AON’s chief medical officer, is chairman of AON’s advisory board and vice chairman of AON’s Board of Managers.

As a leader of AON, what are your top priorities and long-term goals for the organization?
AON is a service organization, physician-led, and patient-centric, with the mission of delivering the highest quality, cost-effective care for patients in a compassionate setting in their own communities. Our platform of services ensures that our providers have the tools necessary to work at an elite level, utilizing the most current data, diagnostic technology, and therapeutic agents. At AON, we are committed to the value proposition that is community oncology, with a goal of continuous improvement and sustainability of the model.

What do you believe are the biggest challenges facing AON and community oncology? What are the strategies for tackling these challenges?
The rapid expansion of data and complexity of data poses a significant challenge for the community oncologist. Remaining current on the latest biomarkers, trial results, and novel therapeutics is now a daunting task. We are addressing this by incorporating actionable biomarker data within the EHR and utilizing decision support tools and AI technologies embedded within the EHR to ensure we are matching the right therapy with the right patient. A second major challenge facing community oncology is the incorporation of cell-based therapies such as CAR-T and bi-specific antibodies for our patients. This will require SOPs and specialized training for our providers. Thirdly, the cost of healthcare remains a concern for patients and payers alike. Our team of value-based experts is striving continuously to identify opportunities to preserve quality care at a lower cost.

How is AON addressing the disparities in cancer care?
Healthcare equity is an ongoing focus for AON. We have an advisory committee focusing on identifying social determinants of health at our practice sites. We determine actionable metrics that we hope will create meaningful change and take steps to implement projects that will remove these barriers to care.

What do you see are the strengths of a national organization such as AON?
AON provides the tools and resources to partnering physicians that enable them to function from a clinical and business perspective at the highest levels within their community. Our physician-led, patient-centric platform at AON empowers our network of providers to become leaders in their field, shaping the future of oncology care as well as ensuring its sustainability.

Meet BeiGene: Taking a Global Approach to the Global Challenge of Cancer

BeiGene Locations Worldwide

BeiGene is a **global, science-driven biotechnology** company committed to creating innovative medicines that are affordable and accessible to far more cancer patients around the world.

We are more than **9,000** colleagues working on **five** continents, with one of the largest oncology research teams in the world. We have enrolled more than **16,000** patients in more than **100** clinical trials in **45** countries in a global approach to developing medicines designed to help reduce costs.

Yet, we are more than a drug discovery and development company. BeiGene is working to improve global health by addressing the broader issue of health inequities and through non-traditional efforts such as our "**Talk About It**" program, which provides essential mental health support for cancer patients.

As we often say at BeiGene, cancer has no borders, and neither do we. This is why we take a global approach in all we do to fight the global challenge of cancer.

UNITED STATES FOOD AND DRUG ADMINISTRATION (FDA) DRUG APPROVALS FOR HEMATOLOGIC MALIGNANCIES FROM APRIL 1, 2022, THROUGH FEBRUARY 12, 2023

FDA approves axicabtagene ciloleucel for second-line treatment of large B-cell lymphoma

On April 1, 2022, the Food and Drug Administration approved axicabtagene ciloleucel (Yescarta, Kite Pharma, Inc.) for adult patients with large B-cell lymphoma (LBCL) that is refractory to first-line chemoimmunotherapy or relapses within 12 months of first-line chemoimmunotherapy. It is not indicated for the treatment of patients with primary central nervous system lymphoma.

FDA approves azacitidine for newly diagnosed juvenile myelomonocytic leukemia

On May 20, 2022, the Food and Drug Administration approved azacitidine (Vidaza, Celgene Corp.) for pediatric patients with newly diagnosed juvenile myelomonocytic leukemia (JMML).

FDA approves ivosidenib in combination with azacitidine for newly diagnosed acute myeloid leukemia

On May 25, 2022, the Food and Drug Administration approved ivosidenib (Tibsovo, Servier Pharmaceuticals LLC) in combination with azacitidine for newly diagnosed acute myeloid leukemia (AML) with a susceptible IDH1 mutation, as detected by an FDA-approved test in adults 75 years or older, or who have comorbidities that preclude use of intensive induction chemotherapy.

FDA approves tisagenlecleucel for relapsed or refractory follicular lymphoma

On May 27, 2022, the Food and Drug Administration granted accelerated approval to tisagenlecleucel (Kymriah, Novartis Pharmaceuticals Corporation) for adult patients with relapsed or refractory follicular lymphoma (FL) after two or more lines of systemic therapy.

FDA approves lisocabtagene maraleucel for second-line treatment of large B-cell lymphoma

On June 24, 2022, the Food and Drug Administration approved lisocabtagene maraleucel (Breyanzi, Juno Therapeutics, Inc.) for adult patients with large B-cell lymphoma (LBCL) who have refractory disease to first-line chemoimmunotherapy or relapse within 12 months of first-line chemoimmunotherapy; or refractory disease to first-line chemoimmunotherapy or relapse after first-line chemoimmunotherapy and are not eligible for hematopoietic stem cell transplantation (HSCT) due to comorbidities or age. It is not indicated for the treatment of patients with primary central nervous system lymphoma.

FDA approves crizotinib for ALK-positive inflammatory myofibroblastic tumor

On July 14, 2022, the Food and Drug Administration approved crizotinib (Xalkori, Pfizer Inc.) for adult and pediatric patients 1 year of age and older with unresectable, recurrent, or refractory inflammatory anaplastic lymphoma kinase (ALK)-positive myofibroblastic tumors (IMT).

FDA approves pemigatinib for relapsed or refractory myeloid/lymphoid neoplasms with FGFR1 rearrangement

On August 26, 2022, the Food and Drug Administration approved pemigatinib (Pemazyre, Incyte Corporation) for adults with relapsed or refractory myeloid/lymphoid neoplasms (MLNs) with fibroblast growth factor receptor 1 (FGFR1) rearrangement.

FDA approves ibrutinib for pediatric patients with chronic graft versus host disease, including a new oral suspension

On August 24, 2022, the Food and Drug Administration approved ibrutinib (Imbruvica, Pharmacyclics LLC) for pediatric patients ≥ 1 year of age with chronic graft versus host disease (cGVHD) after failure of 1 or more lines of systemic therapy. Formulations include capsules, tablets, and oral suspension.

FDA approves teclistamab-cqyv for relapsed or refractory multiple myeloma

On October 25, 2022, the Food and Drug Administration granted accelerated approval to teclistamab-cqyv (Tecvayli, Janssen Biotech, Inc.), the first bispecific B-cell maturation antigen (BCMA)-directed CD3 T-cell engager, for adult patients with relapsed or refractory multiple myeloma who have received at least four prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody.

FDA approves brentuximab vedotin in combination with chemotherapy for pediatric patients with classical Hodgkin lymphoma

On November 10, 2022, the Food and Drug Administration approved brentuximab vedotin (Adcetris, Seagen, Inc.) in combination with doxorubicin, vincristine, etoposide, prednisone, and cyclophosphamide for pediatric patients 2 years of age and older with previously untreated high risk classical Hodgkin lymphoma (cHL). This is the first pediatric approval for brentuximab vedotin.

FDA approves a new dosing regimen for asparaginase erwinia chrysanthemi (recombinant)

On November 18, 2022, the Food and Drug Administration approved a new Monday-Wednesday-Friday dosing regimen for asparaginase erwinia chrysanthemi (recombinant)-rywn (Rylaze, Jazz Pharmaceuticals). Under the new regimen, patients should receive 25 mg/m2 intramuscularly on Monday and Wednesday mornings, and 50 mg/m2 intramuscularly on Friday afternoon. It also is approved to be administered every 48 hours at a dose of 25 mg/m2 intramuscularly.

FDA approves olutasidenib for relapsed or refractory acute myeloid leukemia with a susceptible IDH1 mutation

On December 1, 2022, the Food and Drug Administration (FDA) approved olutasidenib (Rezlidhia) capsules for adult patients with relapsed or refractory acute myeloid leukemia (AML) with a susceptible IDH1 mutation as detected by an FDA-approved test.

FDA grants accelerated approval to mosunetuzumab-axgb for relapsed or refractory follicular lymphoma

On December 22, 2022, the Food and Drug Administration (FDA) granted accelerated approval to mosunetuzumab-axgb (Lunsumio, Genentech, Inc.), a bispecific CD20-directed CD3 T-cell engager for adult patients with relapsed or refractory follicular lymphoma (FL) after two or more lines of systemic therapy.

FDA approves zanubrutinib for chronic lymphocytic leukemia or small lymphocytic lymphoma

On January 19, 2023, the Food and Drug Administration (FDA) approved zanubrutinib (Brukinsa, BeiGene USA, Inc.) for chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL).

FDA grants accelerated approval to pirtobrutinib for relapsed or refractory mantle cell lymphoma

On January 27, 2023, the Food and Drug Administration (FDA) granted accelerated approval to pirtobrutinib (Jaypirca, Eli Lilly and Company) for relapsed or refractory mantle cell lymphoma (MCL) after at least two lines of systemic therapy, including a BTK inhibitor.

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A Discussion with Robert Brodsky, MD, 2023 President, American Society of Hematology Building the Classical Hematology Workforce and Managing Patient Care with Emerging PNH Therapies.

Written by Nicola Donelan

Robert A. Brodsky, MD, is a distinguished expert in classical hematology, and the newly elected president of the American Society of Hematology (ASH). In addition, he is a Professor of Medicine and Oncology and Director of Hematology at John Hopkins University School of Medicine. In a recent interview, Dr. Ruemu Birhiray asked Dr. Brodsky, who happens to be a personal mentor of Ruemu's, to provide some insight on the current ongoing efforts to build the hematology work force, as well as emerging treatments for paroxysmal nocturnal hemoglobinuria (PNH).

TRAINING MORE CLASSICAL HEMATOLOGISTS

There is an urgent need for training classical hematologist due to the rapid pace of advancing therapies. As acting president of ASH, Dr. Brodsky is pushing for increasing single track hematology training. He was instrumental in the launch of ASH's Hematology Focused Fellowship Training Program (HFFTP), a program in which ASH invested $19 million into the development of hematology-specific fellowship programs.

"One result of the amazing progress in treating hematological disease is that there is now a real need to have separate tracks in training," explained Brodsky.

Challenges exist and Dr. Brodsky explained that programs of this type are not possible everywhere due to lack of funding and lack of mentors, but there are several big programs across the US that have the capacity to do these types of cross mentorships. These can allow fellows to be trained in a disease that they may not see a lot of at their local institution.

"I think there's a great need to train people in classical hematology, not at every program in the country, but we certainly need more hematologists that are comfortable with the non-malignant conditions that can be quite devastating," says Brodsky.

EMERGING THERAPIES FOR PNH

Recently some exciting data came out from the APPLY-PNH: Phase III Trial of Iptacopan monotherapy in PNH patients. The results have the potential to change the standard of care for this devastating disease. However, Dr. Brodsky emphasized that caution is needed in embracing this new oral therapy without careful consideration of all the factors involved for each individual PNH patient.

"The data from APPLY is real and that is the exciting part. The scary part is that I'm not so sure that this drug should replace some of the existing drugs," warns Brodsky.

The standard of care for PNH is I.V. infusions of ravulizumab given six times a year. The survival of a PNH patient on ravulizumab is basically the same as an age matched control and most patients (70-75%) become either asymptomatic or mildly symptomatic which is a great patient outcome. There are some remaining patients (20-25%) who either have moderately or significantly symptomatic anemia, and here there is room for improvement. What worries Dr. Brodsky about the short acting oral drugs like iptacopan and danicopan is the issue of how to deal with a patient who comes in and they present with thrombosis.

"What people forget is that the leading cause of death in PNH used to be thrombosis. And now no one clots anymore with ravulizumab," emphasized Dr. Brodsky.

"Are you really going to reach for that oral drug when you don't know the long-term data of thrombosis. Probably not," warned Brodsky.

Dr. Brodsky went on to explain why he says caution must be taken with using these exciting oral drugs with alternative pathways such as danicopan and iptacopan and even pegcetacoplan.

"They have different targets than ravulizumab, they target C3 and Factor B and these are acute phase reactants, so these protein levels in the blood will go up in the setting of a severe infection or during surgery and may no longer be blocked as they would at steady state levels by these drugs," he described.

However, Dr. Brodsky believes that these new drugs will change the standard of care for PNH patients. He advises that they can be used in patients who primarily have hemolytic PNH with no overt thrombosis, and in patients who have a good reputation of being compliant.

"Taking a drug twice a day might be risky even in compliant patients, missing one dose you'll probably be ok, but missing 2 doses will lead to massive hemolysis, leading to massive thrombosis and that is what worries me," he warned.

These oral therapies need to be taken consistently and a lot of these are mail in drugs. Therefore, patients will need to ensure that their supplies do not run out. Patients on ravulizumab are not at risk for thrombosis even if they come in a week late for treatment, but this is not the case for the oral therapies.

"Sequencing these new drugs needs to be figured out carefully, but they will undoubtedly play a role in treatment as they are great drugs with great targets," concluded Brodsky.

Dr. Bihiray's final and very poignant comment to Dr. Brodsky really brought the point home about what is going to be extremely critical for PNH patient care moving forward.

"That is why we need people like you to advise us, so that we can do the right thing by our patients," said Dr. Birhiray.

3 ways to contact Indy Hematology Review

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Reference: 1. Sharman JP, Egyed M, Jurczak W, et al. Poster presented at ASCO Annual Meeting; June 3-7, 2022. Abs 7539.

AstraZeneca

Indy Hematology Education, Inc.
Achieving tomorrow's outcomes through education today™

Indy Hematology Education, Inc, is a 501(c), non-profit corporation, incorporated on February 15, 2010, in the State of Indiana, with the following purposes:

(a) Raise awareness and provide education regarding hematology and oncology diseases and disorders
(b) To encourage youth to pursue careers in hematology and oncology, and
(c) To connect individuals suffering from or affected by hematology and oncology diseases and disorders to organizations, programs, and service providers.

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EMERGING THERAPIES

Emerging Therapies in Hematologic Malignancies and Hematologic Disorders Clinical Significance of Current Data: "My Thoughts" 2023

PRACTICE Changing:

- Blinatumumab + Chemotherapy Consolidation in MRD negative Ph Negative ALL
- Ponatinib plus reduced intensity chemotherapy in Ph positive ALL
- Avoiding remission induction and proceeding with immediate allotransplantation in Relapsed/ Refractory AML.
- MATRix chemotherapy followed by HDC/ASCT in Primary CNS lymphoma.
- Ibrutinib + chemoimmunotherapy as substitute for ASCT in younger patients with MCL.
- Iptacopan in Paroxysmal Nocturnal Hemoglobinuria with residual anemia residual anemia on anti-C5 therapy.

Practice Confirming

- Gemtuzumab Ozogomycin in Core-Binding AML
- Post-Transplant Cyclophosphamide + TAC + MMF vs TAC + MTX for Prevention of GVHD following Reduced-Intensity conditioning allogeneic SCT.
- Covalent BTKi therapy in CLL: Zanabrutinib

Potentially Practice Changing:

- Pirtobrutinib in relapsed and refractory Waldenström Macroglobulinemia
- Efgartigimod in Adult Primary Chronic or Persistent ITP
- GPCR5D x CD3 Bispecific antibody Talquetamab in RRMM

Stay Tuned

- Asciminib in patients failing to reach molecular targets in CML after initial TKI therapy.
- CD20 x CD3 Bispecific antibodies plus chemo-immunotherapy as initial therapy for DLBCL
- Bispecific antibodies in R/R lymphoma and RRMM
- Polatuzumab Vedotin + R-ICE (PolaR-ICE) As Second-Line Therapy in R/R DLBCL
- Epcoratimab after Richter's transformation in CLL

Ruemu E. Birhiray, MD
Chair, Indy Hematology Review

JOIN US FOR THE 21ST ANNUAL INDY HEMATOLOGY REVIEW SATURDAY, FEBRUARY 24, 2024 THE WESTIN INDIANAPOLIS

An Interview with Dr. Jennifer Woyach, MD
Improving Treatment in Chronic Lymphocytic Leukemia

Written by Nicola Donelan

At the 20th Indy Hematology Review meeting, Dr. Woyach will be giving the Annual Steven Coutre Chronic Lymphocytic Leukemia (CLL) Memorial Lecture. A truly fitting speaker selection as she is extremely passionate about improving CLL treatments through her ongoing research and providing cutting edge therapies for her patients. Dr. Woyach is a hematologist-oncologist at The James Cancer Hospital and Solove Research Institute in Columbus Ohio where she specializes in treating patients with blood cancers, particularly chronic lymphocytic leukemia (CLL) and B-cell lymphomas. She also serves as a professor in the Division of Hematology at The Ohio State University. Dr. Woyach's main research interests focuses on developing new therapies for patients with CLL and figuring out mechanisms of resistance and using that knowledge to develop rational strategies, to treat patients with CLL and Richter's Transformation. We recently had a chance to speak to Dr. Woyach, not only about her research and clinical work, but also about her career journey, what motivates her, and how she views the hematology field as an option for medical and doctorate students.

What led you to choose hematology as your specialty?
I initially chose to study Internal Medicine because I enjoyed the breadth of medicine that you get to practice and the way that internists approached clinical problems. I was then drawn to hematology/oncology because I liked that you could take care of patients and their families for long periods of time. That you could really form a connection with the patients and have a lot of longitudinal care. I also was drawn to the scientific advances that were taking place in hematology/oncology, and the way the field was quickly changing. For leukemia and CLL specifically, I felt that there was the opportunity to be on the forefront of new treatments and new discoveries.

Can you tell us about your career journey?
When I first thought about a career as a physician, I wanted to exclusively take care of patients. Once I was exposed to clinical trials as a resident and fellow, I decided that I would do clinical research in order to make an impact on patients that went beyond just the patients I could see in my clinic. Then, when I was a fellow, I started to work in the laboratory of my mentor Dr. John Byrd and really enjoyed it. I decided that in addition to doing clinical research, I wanted to be able to do research in the laboratory and try to do translational research that could bring new treatments to patients through clinical trials.

What motivates you on a daily basis?
My patients motivate me on a daily basis. Although there have been a lot of advances in the treatment of CLL, there remain a number of open questions and unmet clinical needs. There are lots of patients who still need us to be doing research in the lab and research in the clinic and this motivates me every day.

Advice would you give to medical/ doctorate interested in a hematology career?
I think that being a hematologist is the best job in the world. It gives you the opportunity to combine science and taking care of patients. Doing research is particularly rewarding, because you can actually see the impact of what you're doing. When you see clinical trials that are using drugs coming forth from the laboratory and being part of clinical trials that are really advancing the care of a particular disease, that is very rewarding.
Any words of wisdom to women considering this field?
Academic hematology/oncology is an excellent career for both men and women. In my hematology division at Ohio State, we have over 50% women, and many people with young children. I think hematology/oncology can see like a daunting field because there is so much to learn and treatments change rapidly, but it is also extremely rewarding. Academic hematology in particular also can offer more flexibility over community practice because you are not necessarily seeing patients every day, and there is more flexibility in when you can work to get your academic projects completed. I don't think that there is anything specific about the culture of hematology that is off-putting to women. Even though there are more men in the field currently, I think things are becoming more balanced over time.

What areas of research do you focus on currently?
My research focuses on developing new therapies for patients with CLL. As part of this, in the laboratory I try

to find out why some patients become resistant to our current therapies, and then use that knowledge to develop rational strategies to treat patients with CLL. My clinical research focuses on doing clinical trials of all phases from first in human studies to phase III trials.

What treatments that are available right now, do you think are the most promising for patients with CLL?

There's a lot of very exciting research that's going on in CLL right now. Some of the most promising treatments in clinical trials are novel BTK an BCL2 inhibitors which are being developed to improve upon the efficacy and safety of our current available options. There are also novel therapies that interrupt the B cell receptor signaling pathway downstream of BTK that are very exciting. Finally, like many other diseases, the CLL field is very excited about strategies using the patient's own immune system to help eradicate the disease, including bispecific antibodies and CAR T cells. These immune based strategies have lagged a little in CLL compared to other hematologic malignancies due to the immune dysfunction that is a hallmark of CLL, however, with improvements in these therapies, patients with CLL are really being able to benefit too.

And finally, what are you looking forward to at the 20th hematology review meeting?

The Indy Hematology Review is always a great meeting. They put together an exciting lineup of speakers who are all experts in their field, and it's amazing to get to hear many of these people talk about what they feel are the most exciting developments in their particular subspecialty. There's lots of time built in for networking so it's always fun for the attendees and the speakers to interact with each other, both discussing clinical cases and making new connections.

It's especially exciting for me, because I'm not very far away being just in Columbus, Ohio, so I share patients with and talk frequently with many of the doctors that come to this meeting. That is one of the things that I look forward to each year I have participated in this meeting.

CONTINUING EDUCATION INFORMATION

PHYSICIANS

In order to receive CE, you must attend the entire Symposium from 8:00 am – 7:00 pm. Successful completion of this CME activity requires participants to complete a Post-Evaluation.

Successful completion of this CME activity, which includes participation in the evaluation component, enables the participant to earn up to 9.25 Medical Knowledge MOC points in the American Board of Internal Medicine's (ABIM) Maintenance of Certification (MOC) program. It is the CME activity provider's responsibility to submit participant completion information to ACCME for the purpose of granting ABIM MOC credit.

Learning Objectives (ACCME, ANCC, ACPE)

1. Improve patient outcomes by incorporating the most current therapies for Acute Myeloid Leukemia and Acute Promyelocytic Leukemia.
2. Explain how Apollo and the Indianapolis Oracle will impact the treatment of Myelodysplastic Syndromes.
3. Predict the future of Chronic Myeloid Leukemia and how it might impact patient care strategies.
4. Identify the emerging treatment options for Multiple Myeloma and describe how to put these treatment options into practice.
5. Review the most current and evolving treatment options for Waldenstrom's Macroglobulinemia
6. Adjust their treatment strategies for patients with Amyloidosis to include emerging therapies as appropriate.
7. Evaluate the diagnosis for cellular blood disorders including how best to treat disorders such as Polycythemia Vera and Essential Thrombocytosis.
8. Discuss the most current research for the diagnosis and treatment of Myelofibrosis, Philadelphia Chromosome Negative MPN's and FGFR Mutant Myeloid Neoplasms
9. Improve the management of benign hematology consultations and treatment options for Coagulopathy, Cytosis and Cytopenias in practice.
10. Describe the current controversies and updated treatment recommendations for patients with Acute Lymphoblastic Leukemia and Lymphoblastic Lymphoma.
11. Choose the appropriate therapy or therapies for patients with Chronic Lymphocytic Leukemia.
12. Devise a treatment strategy that may improve outcomes for patients with Aggressive B and T Cell Lymphomas
13. Identify when Hematopoietic Transplantation and Cellular Therapies are an appropriate treatment strategy.

Physician Accreditation Statement

This live activity has been planned and implemented in accordance with the accreditation requirements and policies of the Accreditation Council for Continuing Medical Education (ACCME) through the joint providership of Purdue University College of Pharmacy and Indy Hematology Education, Inc. Purdue University is accredited by the ACCME to provide continuing medical education for physicians.

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Purdue University College of Pharmacy designates this live activity for a maximum of 9.25 AMA PRA *Category 1 Credit(s)™*. Symposium – 8:00 am – 7:00 pm. Purdue University College of Pharmacy designates this live activity for a maximum of 1.25 AMA PRA *Category 1 Credit(s)™* (Town Hall Interactive Meeting – 7:30 – 8:45 pm). Physicians should claim only the credit commensurate with the extent of their participation in the activity.

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Disclosures will be provided prior to the start of the activity. All relevant conflicts of interest will have been mitigated prior to the start of the activity. None of the planners, reviewers, Indy Hematology Education, and Purdue University College of Pharmacy staff have relevant financial relationship(s) with ineligible companies to disclose unless listed below.

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PHARMACISTS

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Pharmacists Accreditation Statement

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Symposium: 8:00 am – 7:00 pm.

Universal Activity Number (UAN): 0018-9999-23-002-L01-P

This program is approved for 9.25 contact hours (0.925 CEU's).

Town Hall Interactive Meeting: 7:30 pm – 8:45 pm.

Universal Activity Number (UAN): 0018-9999-23-001-L01-P

This program is approved for 1.25 contact hours (0.125 CEU's).

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All participants that successfully complete the CME, CNE or CPE activity, and completes the post evaluation component, no later than **April 7, 2023** is eligible to receive Continuing Education Credits. In addition, participants wanting Medical Knowledge MOC points in the American Board of Internal Medicine's (ABIM) Maintenance of Certification (MOC) program must also complete the additional post survey, no later than **April 7, 2023**. All Continuing Education Credit/MOC is forfeited if participant does not complete post evaluation and/or survey no later than **April 7, 2023. NO EXCEPTIONS!**

NOTE: While it offers CME credits, this activity is not intended to provide extensive training or certification in the field.

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