A New, Harmonized Approach Takes a Stand Against Rising Rates and Poor Outcomes for Cancer in Sub-Saharan Africa

NCCN has debuted brand new NCCN Harmonized Guidelines for Sub-Saharan Africa in Kigali, Rwanda. These targeted recommendations, based on the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines), were created in a joint effort by NCCN and the African Cancer Coalition, and presented for the first time as part of the African Organisation for Research and Training in Cancer (AORTIC) conference. The NCCN Harmonized Guidelines creation is part of a collaborative effort to combat the skyrocketing cancer rates and unique care circumstances in Sub-Saharan Africa. The collaboration also includes the American Cancer Society (ACS) and the Clinton Health Access Initiative (CHAI).

“There are unique challenges for patients with cancer in this part of the world, but also many reasons to be hopeful,” said Robert W. Carlson, MD, Chief Executive Officer, NCCN. “Less than 10% of people with cancer in Sub-Saharan Africa currently receive pain relief, chemotherapy, or radiation.¹ But the endless creativity, compassion, and know-how of the oncologists in the African Cancer Coalition is inspiring. By working together across the global community, we can make tremendous strides to address the rising mortality and poor early detection rates.”

“This extraordinary collaboration between African oncology experts and NCCN will make it easier for oncologists to access up-to-date clinical guidance and ensure the highest standard of care for their patients,” said Meg O’Brien, PhD, Managing Director, Global Cancer Treatment, ACS. “The NCCN Harmonized Guidelines empower patients and providers to focus on what is practical, achievable, and effective at present, while providing a template for future improvements and advances.”

The African Cancer Coalition comprises more than 40 oncologists from 12 countries throughout Sub-Saharan Africa. Working with NCCN Guidelines Panel Members, they created the first 8 NCCN Harmonized Guidelines for Sub-Saharan Africa.

“This collaboration provides an opportunity to bring together leading African oncology experts and NCCN experts to develop clinical guidance that ensures our patients get access to the highest quality cancer care possible,” said Jackson Orem, MD, Executive Director, Uganda Cancer Institute, and co-chair of the African Cancer Coalition.

The NCCN Harmonized Guidelines offer 2 tiers of treatment recommendations for breast, cervical, and prostate cancers, as well as B-cell lymphomas, chronic lymphocytic leukemia/small lymphocytic lymphoma, Kaposi sarcoma, adult cancer pain, and palliative care. The different versions provide specific recommendations depending on access to resources like radiation equipment or laparoscopic surgical tools.

“It was a gratifying and inspiring experience to collaborate with and learn from our Sub-Saharan colleagues, who do hands-on work solving problems for patients every day,” said Wui-Jin Koh, MD, Seattle Cancer Care Alliance. Dr. Koh was one of several NCCN Leadership and Guidelines Panel Members to travel to parts of Africa for this initiative, along with Dr. Carlson; Joan McClure, MS, NCCN; Maria Dans, MD, Siteman Cancer Center at Barnes-Jewish Hospital and Washington University School of Medicine; James Mohler, MD, Roswell Park Cancer Institute; and Andrew Zelenetz, MD, PhD, Memorial Sloan Kettering Cancer Center.

Dr. Koh continued: “While these physicians know how to provide top-level care, they are often hamstrung by a lack of access to equipment and long wait times before treatment. Working together, we were able to distill the most important elements of care management, and prioritize treatments that provide effective outcomes even when resources are limited. For example, in cervical cancer, which has a very high incidence in this region, combining chemotherapy and surgery helped patients where radiation therapy wasn’t available.”

CHAI also worked closely with NCCN and ACS to support the harmonization process and is engaging the Africa Cancer Coalition more broadly around access to medicines. CHAI recently worked with ACS to develop partnerships with 2 leading drug

doi:10.6004/jnccn.2017.0179

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manufacturers, enabling 6 countries in Sub-Saharan Africa to realize significant savings on the procurement of 16 essential chemotherapies, while simultaneously facilitating a shift to high-quality medicines.

In many ways, this initiative is modeled after the success of past HIV efforts, and also necessary because of them. As life expectancy increases in the area, more people are being diagnosed with various cancers. This project also inspired the creation of brand new NCCN Guidelines for AIDS-Related Kaposi Sarcoma, which accounts for 12% of cancer diagnoses for people living with HIV in the United States,² but occurs much more frequently in Sub-Saharan Africa.

“Developing high-quality, standardized treatment guidelines was an important step in the early days of scaling up HIV treatment. These cancer treatment guidelines will help to improve quality of care and organize the market around optimal cancer treatment regimens,” said CHAI CEO Ira Magaziner.

“This work fits perfectly with our vision to define and advance high-quality, high-value cancer care across the world,” said Dr. Carlson. “We’re proud to have played an important role in this collaboration to create guidelines that help people with cancer secure the best treatment they can, no matter where they live.”

References

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The Importance of a Partner in Cancer Therapy

Whether or not a patient is married is an understood predictor in clinical outcomes, including in patients with cancer. Although researchers know that partnered patients have better overall survival (OS) than unmarried patients, it is unknown exactly why.

To further investigate this issue, Christine M. Veenstra, MD, MSHP, medical oncologist at University of Michigan Comprehensive Cancer Center, set out to study outcomes among patients with stage III colon cancer, comparing the treatment and outcomes of patients who were married or partnered against those who were not.

Dr. Veenstra was a 2015 recipient of the NCCN Foundation Young Investigator Award, which funds promising researchers early in their careers.

The Partnered Patient Population

Veenstra and colleagues examined medical records for nearly 400 patients within the Michigan Cancer Research Consortium with stage III colon cancer, noting their partnered status, and compared the treatment that the patients received to the recommendations from NCCN as outlined in the 2015 version of the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines) for Colon Cancer.

According to Dr. Veenstra, because the NCCN Guidelines for stage III resected colon cancer are clear, comprehensive, and evidence-based, they provide an excellent case for investigating concordance. The protocol outlined in the 2015 guidelines included surgery, followed by 6 months of adjuvant chemotherapy, preferably a 2-drug combination chemotherapy. Although 85% of the patients studied received either combination or single-agent chemotherapy, partnered patients were far more likely to complete the 6-month course, perhaps also increasing their likelihood of OS.

“We found that patients who had a partner were almost twice as likely to complete the full 6 months of chemotherapy. This finding is important as it points to a possible mechanism for improved outcomes that we had not recognized earlier,” said Dr. Veenstra.

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Although the state of partnership does not change the physical characteristics of one's cancer or the likelihood of their response to treatment, there are theories for this disparity. Regarding the specific treatments outlined in this study, the most common side effect and reason patients gave for stopping treatment was neuropathy.

"Partners may help patients manage and cope with the physical side effects of treatment, as well as provide important encouragement and positive support that unpartnered patients do not necessarily have," explained Dr. Veenstra. She also noted that general support could be a factor, such as someone to provide transportation or fill prescriptions at the pharmacy.

Bridging the Gap

Now that Veenstra et al has identified a mechanism behind improved outcomes for a particular patient population, work can immediately be done to improve adherence to NCCN Guidelines—concordant care in unpartnered patients. One way to do this, Dr. Veenstra says, is to train clinicians to recognize and be aware of the risks facing unpartnered patients.

"The unpartnered patient population is at risk for not completing or receiving recommended care. We must work to ensure that support systems are in place so that patients are able to stay the course of treatment," Dr. Veenstra said. These support systems can include extended family and friends, as well as local support groups and patient advocacy organizations.

Dr. Veenstra acknowledged that there are a few more steps to her research. Next, she plans to work directly with patients and their partners. "I am interviewing patients and their partners about the role the partners play and its impact on the patient—I want to be able to look at this from the couple's perspective—in their own words," said Dr. Veenstra.

She also plans to extend her research across the cancer care continuum, particularly surveillance of high-risk survivors and their partners, to better understand how clinicians can intervene to improve quality of care.

Advancing the Care of Patients With Cancer

In 2015, Dr. Veenstra was 1 of 5 grant recipients through the NCCN Foundation Young Investigator Award program, which funded her research for this project. The NCCN Young Investigator Awards provide vital funding to some of the nation's top next-generation cancer researchers guiding the course of treatment innovation and advancement. Moreover, the program makes it possible for junior faculty to develop the unique skillset necessary in today's competitive research environment by enabling them to balance research and clinical duties early in their careers, as well as introducing them to a network of senior investigators from leading cancer centers.

Through the grant program, young investigators, like Dr. Veenstra, are nominated by leaders at NCCN Member Institutions for their dedication to discovering cutting-edge breakthroughs and interventions in cancer care.

"The NCCN Foundation Young Investigator Award has been critical at this early point in my research career. It has provided the support for the study, as well as protected my time as a researcher to build my research program in this area so that I can grow to become an independent researcher," said Dr. Veenstra.

Dr. Veenstra notes that funding from the NCCN Foundation allowed her to advance her research, and she has since received an NCI Cancer Prevention, Control, Behavioral Sciences, and Population Sciences Career Development Award (K07), which is supporting the aforementioned interview trial.

"It is important at an early stage of a research career to have the opportunity to grow and attain grants to build and expand studies. It's the Young Investigator Award that protects this time for me," said Dr. Veenstra.

Dr. Veenstra's study, "Partnered Status & Receipt of NCCN Guideline—Concordant Colon Cancer Care," was presented at the General Poster Session during the NCCN 22nd Annual Conference in March 2017.

More information is available at JNCCN.org.

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NCCN Annual Congress Explores Latest Advances in Treating Hematologic Malignancies

On Friday, October 6, and Saturday, October 7, 2017, NCCN hosted its 12th Annual Congress: Hematologic Malignancies in San Francisco, California. The congress was moderated by Ranjana H. Advani, MD, Stanford Cancer Institute, Vice-Chair of the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines) Panel for Hodgkin Lymphoma and member of the NCCN Guidelines Panel for B-Cell Lymphomas; and Andrew D. Zelenetz, MD, PhD, Memorial Sloan Kettering Cancer Center, Chair of the NCCN Guidelines Panel for B-Cell Lymphomas.

The didactic presentations and patient case studies focused on the current standard of care and recent advances in the management of hematologic malignancies, including follicular lymphoma (FL), Hodgkin lymphoma (HL), multiple myeloma (MM), myeloproliferative neoplasms (MPNs), chronic lymphocytic leukemia (CLL), acute myeloid leukemia (AML), and acute lymphoblastic leukemia (ALL).

Opening remarks by Dr. Advani on Friday were followed by 3 didactic presentations. Dr. Zelenetz reviewed the updates to the 2016 WHO classification of lymphoid neoplasms, focusing on the key changes to the classification of aggressive B-cell lymphomas. Determination of the cell of origin (germinal center B-cell vs activated B-cell) either by immunohistochemistry (IHC) or gene expression profiling is now required for the diagnosis of subtypes of diffuse large B-cell lymphoma, Dr. Zelenetz explained. Double-hit or triple-hit B-cell lymphomas have been reclassified as high-grade B-cell lymphomas with *MYC* and *BCL2* and/or *BCL6* rearrangements. Therefore, it is now important to evaluate *BCL2* and *MYC* protein expression by IHC and perform molecular analysis to detect *MYC*, *BCL2*, or *BCL6* gene rearrangements. These changes provide greater precision for the diagnosis, allowing for the development of more appropriately targeted therapies; however, this could also mean that certain groups of patients may be excluded from clinical trials evaluating specific targeted therapies, Dr. Zelenetz concluded.

Jane N. Winter, MD, Robert H. Lurie Comprehensive Cancer Center of Northwestern University, discussed updates to the treatment of FL. She provided an overview of current treatment options and reviewed data from clinical trials evaluating novel agents for the treatment of relapsed/refractory (R/R) FL—PI3K inhibitors (duvelisib and copanlisib), checkpoint inhibitors (pembrolizumab), BCL-2 inhibitors (venetoclax), and antibody-drug conjugates (polatuzumab vedotin). Although overall survival (OS) has improved considerably for the vast majority of patients with FL, survival remains poor for the subgroup of patients who progress within 24 months of initial treatment. Dr. Winter highlighted the need to identify these high-risk patients and implement novel treatment strategies to improve their outcomes.

Dr. Advani provided an overview of standard and emerging options for the treatment of HL. Noting that the management of localized HL is a success story with high cure rates, she stressed that there is a need for therapeutic options in advanced disease settings. Using a case study, Dr. Advani gave an overview of standard treatment options for patients with R/R classical HL, including a list of chemotherapy regimens followed by autologous stem cell transplant (ASCT), and immunomodulatory agent, brentuximab vedotin. Recent results from the ECHOLON 1 trial suggest a role for brentuximab vedotin in frontline therapy for patients with advanced-stage classical HL when combined with the standard ABVD (doxorubicin, bleomycin, vinblastine, and dacarbazine) regimen. Dr. Advani also reviewed data for the checkpoint inhibitors nivolumab and pembrolizumab. Ongoing clinical trials are examining the prognostic impact of metabolic tumor volume and the utility of lenalidomide, ibrutinib, ruxolitinib, panobinostat, or chimeric antigen receptor (CAR) T-cell therapy as options for R/R HL. Because new technologies are improving the understanding of the genetics of classical HL, Dr. Advani concluded that some of the future challenges with these novel and emerging therapeutic options include access to resources and optimal use of treatments that target genetic abnormalities.

The session on Friday concluded with the first series of patient case studies and panel discussion presented by Mark W. Clemens II, MD, The University of Texas MD

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Anderson Cancer Center; Youn H. Kim, MD, Stanford Cancer Institute; and Dr. Zelenetz. The panelists discussed the diagnosis, workup, and treatment of splenic marginal zone lymphoma and 2 rare subtypes of T-cell lymphomas (breast implant–associated anaplastic large cell lymphoma and cutaneous T-cell lymphoma [Sézary syndrome]).

On Saturday morning, sessions commenced with a presentation on the management of lymphoma survivors. Sharyn L. Kurtz, PA-C, MPAS, Dana-Farber/Brigham and Women's Cancer Center, provided a detailed overview of the various types of long-term/late effects of curative treatment involving multiple organ types. She also provided recommendations for periodic screening to identify and manage treatment-related toxicities in survivors of HL and non-Hodgkin's lymphomas. She stressed the importance of providing a treatment summary and care plan at the completion of treatment, communicating with the community physician, developing evidence-based survivorship practices, and underscored the growing role for advance practice providers in the management of lymphoma survivors.

This was followed by patient case studies and interactive panel discussions on plasma cell neoplasms in which the panelists, Shaji K. Kumar, MD, Mayo Clinic Cancer Center; Sandy W. Wong, MD, UCSF Helen Diller Family Comprehensive Cancer Center; and Natalie S. Callandar, MD, University of Wisconsin Carbone Cancer Center, focused on the key aspects of diagnosis, management, and special considerations for solitary plasmacytoma, systemic light chain amyloidosis, and MM in elderly patients.

The case studies were followed by 3 presentations encompassing the overall management of patients with MM. Dr. Kumar presented the strategies for treating transplant-eligible, newly diagnosed patients with MM. He outlined important steps in the management of MM—accurate diagnosis, risk stratification of the individual patient, and durable disease control. Currently, the standard of care for this patient population is a triple-drug regimen with an immunomodulator (IMiD) and a proteasome inhibitor (PI). Data from the phase III SWOG S077 trial demonstrated that the triple-drug regimen bortezomib/lenalidomide/dexamethasone (VRD) as initial therapy improved progression-free survival and OS compared with the doublet (lenalidomide/dexamethasone). Newer combinations of IMiDs and PIs are being explored to obtain better responses and increase tolerability. Based on the promising data from phase II trials of carfilzomib/lenalidomide/dexamethasone (CRD) as initial therapy, there is an on-going phase III trial (E1A11) currently recruiting patients to compare VRD versus CRD as initial therapy. Similarly, another phase III trial (TOURMALINE MM-2) is evaluating the efficacy of ixazomib/lenalidomide/dexamethasone compared with lenalidomide/dexamethasone. Dr. Kumar also pointed out that ASCT continues to play an important role in consolidating, deepening, and maintaining response to initial treatment. The results of the IFM 2009 study clearly show the benefit of transplant in all groups of patients with the response being durable in those with no minimal residual disease (MRD) after initial therapy. Maintenance therapy further helps optimize responses achieved by primary therapy and ASCT. A recent meta-analysis of 3 randomized clinical trials found that lenalidomide maintenance after ASCT significantly improved OS compared with controls. Dr. Kumar concluded his presentation by stressing the importance of administering supportive care in patients with MM.

“Despite major and continuing treatment interventions, MM remains incurable for most patients,” shared Dr. Callandar, who discussed the appropriate evaluation for R/R MM and management strategies. She pointed out the rapid additions of new drugs and combinations to the treatment armamentarium over the past 2 years, which have contributed to the dramatic improvement in survival rates of patients with MM. To help select appropriate treatment from the large list of options available, she mentioned that the NCCN panel has classified the regimens into the following categories: preferred regimens, other recommended regimens, and regimens useful under certain circumstances. Dr. Callandar illustrated with case studies how to tailor treatment approaches based on biology, frailty, comorbidities, lines of treatment, etc. She emphasized that clinical trials should always be considered, as there are many underway evaluating new drugs with new mechanisms of action, and that the treatment paradigm continues to evolve.

The session on MM concluded with a talk by Kathleen Colson, RN, BSN, Dana-Farber Cancer Institute, focusing on the management of common complications related to MM and its treatment. In her presentation, she described supportive care measures for common

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clinical manifestations of MM, such as bone-related issues, renal dysfunction, anemia, and infections. She highlighted the adverse effects associated with the newest agents such as daratumumab and elotuzumab in order to help anticipate and effectively manage them, thereby improve patient outcomes.

Thomas LeBlanc, MD, MA, Duke Cancer Institute, discussed palliative and end-of-life care in hematologic malignancies, with the main objective of his presentation being to dispel inaccurate perceptions of palliative care. He started his talk by defining palliative care as “a specialized medical care for people facing a serious illness,” with the focus on providing patients with symptom and stress relief and a goal of improving quality of life for the patient and caregiver. Despite accumulating evidence demonstrating the benefits of adding palliative care, he noted that more work is needed to better understand the unique needs of patients with hematologic malignancies, and healthcare teams need to partner together to address them.

The afternoon session commenced with the patient case studies and panel discussion in which the panelists Ruben A. Mesa, MD, UT Health San Antonio Cancer Center; Neil P. Shah, MD, PhD, UCSF Helen Diller Family Comprehensive Cancer Center; and William G. Wierda, MD, PhD, The University of Texas MD Anderson Cancer Center; discussed the management of disease progression of MPN to AML, criteria for the discontinuation of tyrosine kinase inhibitor therapy for chronic myeloid leukemia (CML) in carefully selected patients, and the role of maintenance therapy in CLL.

Dr. Mesa presented the recommendations included in the recently published NCCN Guidelines for MPNs for the diagnosis, risk stratification, and treatment of polycythemia vera (PV) and essential thrombocythemia (ET). The primary goal of therapy is to control disease-related symptoms and decrease the risk of vascular events, he noted. Therefore, quantification of symptoms through a patient-reported assessment tool should be an essential part of the management of these patients, he emphasized. Dr. Mesa concluded his talk with a brief mention of novel treatment options that are being evaluated in clinical trials.

Dr. Wierda reviewed the clinical data supporting the current treatment options for CLL and outlined potential strategies for the sequencing of therapy for R/R disease. Del(17p) or *TP53* mutation are more common in R/R disease and CLL with del(17p) or *TP53* mutation is not very responsive to chemoimmunotherapy. Therefore, it is essential to evaluate mutation status before initiating treatment for R/R disease, emphasized Dr. Wierda. In addition, it is also important to consider prior treatment (chemoimmunotherapy vs ibrutinib), duration of remission, and refractoriness of the disease prior to treatment, Dr. Wierda explained. Long-term durable disease control is the goal of treatment for R/R disease, and appropriate sequencing of therapy could prolong survival in this patient population, he concluded.

David G. Maloney, MD, PhD, Fred Hutchinson Cancer Research Center/Seattle Cancer Care Alliance, presented on new agents being used or considered for the management of ALL, particularly for R/R disease. Dr. Maloney began by emphasizing that adult patients with ALL experience poorer survival rates and there is a need for therapeutic agents that effectively combat relapsed or refractory disease. Data was presented for immunotherapies including rituximab, inotuzumab ozogamicin, blinatumomab, and CAR T-cells, given the recent approvals of the last 3 agents as options for R/R disease. Combining rituximab and inotuzumab ozogamicin with standard chemotherapy has shown decreased relapse rates and improved survival rates. Dr. Maloney stressed the need for close monitoring of toxicity profiles and speculated on possible causes of neurotoxicity associated with immunotherapies. Ongoing clinical trials with CAR T-cell therapy are seeking to improve CAR T-cell persistence and thereby improve disease remission rates. For these new therapies, Dr. Maloney noted that a challenge would be determining how to sequence treatment, with the overarching goal of decreasing the need for allogeneic transplant.

Bruno Medeiros, MD, Stanford Cancer Institute, gave an overview of new and emerging agents used as targeted therapy in the management of AML. “For the first time in 2 decades, we have new options for AML,” Dr. Medeiros stated, which ideally should decrease relapse rates in patients achieving a remission, improve response rates in patients with chemoresistant phenotypes, and decrease toxicities associated with current

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therapeutic strategies. He presented clinical data for several targeted therapies including FLT3 and IDH inhibitors (midostaurin, crenolanib, gilteritinib, quizartinib, enasidenib, or ivosidenib), hypomethylating agents (guadecitabine or oral azacitidine), immunotherapies (gemtuzumab ozogamicin, bispecific T-cell engager [BiTE]/DART molecules, vadastuximab talirine) and new delivery methods for cytarabine and daunorubicin (CPX-351) used for upfront therapy and relapsed disease. For example, the addition of the FLT3 inhibitor, midostaurin, to conventional therapy increased complete remission rates in patients with AML aged <60 years. A few clinical trials are in progress using CAR T-cell therapy, although Dr. Medeiros noted that dual-targeting strategies might enhance the specificity and decrease off-target effects observed with this approach. Dr. Medeiros concluded that the current challenge would be determining effective use and sequencing of these new agents. Additionally, with several new promising agents in late-stage development, these agents have an immense potential to impact AML management.

An engaging 2-part talk on controversies that surround MRD monitoring in AML was delivered as the last presentations. Jessica K. Altman, MD, Robert H. Lurie Comprehensive Cancer Center of Northwestern University, and member of the NCCN Guidelines Panel for AML, set the stage by defining the concept of MRD and outlining steps that would lead a clinician to consider MRD assessment as a means of monitoring patient response to therapy. Dr. Altman postulated that ideally, MRD should provide prognostic information to the presenting features and guide risk stratification during disease management. She then provided a review of the current methods used to assess MRD, including flow cytometry and PCR-based assays; however, a lack of defined markers and lack of standardized methods and disease thresholds represent challenges to their effective use in MRD monitoring. In addition, some data suggest that patients without detectable MRD may still relapse. Dr. Altman noted that emerging technologies with increased sensitivities, including next-generation sequencing-based assays and digital PCR, might address this. Richard M. Stone, MD, Dana-Farber Cancer Institute, Vice-Chair of the NCCN Guidelines Panel for Myelodysplastic Syndromes and member of the NCCN Guidelines Panel for AML, highlighted that in addition to the lack of standardization, high costs and the ambiguity of the potential impact on prognosis and clinical decision-making also present major barriers to the effective use of MRD assessment in the management of AML. Dr. Stone presented clinical data to support two potential ways to enhance the utility of MRD in AML: (1), the development of therapeutic agents that eradicate measurable residual disease, and (2) determine the efficacy of double umbilical cord transplant at diminishing poor prognosis based on MRD risk stratification. Both Drs. Altman and Stone concluded that overall, MRD assessment is important to include in clinical studies and there is a need for standardized guidelines to inform therapeutic decisions.

The congress concluded with closing remarks from Drs. Zelenetz and Advani.

Accredited materials from the congress will be available shortly through the NCCN Continuing Education Portal at education.nccn.org.

The NCCN 13th Annual Congress: Hematologic Malignancies is scheduled for Friday, September 21, and Saturday, September 22, 2018, in New York, New York.