Featuring

- NCCN Reimbursement Resource Room
  Learn about reimbursement help and services available.

- Health Information Technology Row
  Learn how HIT tools use NCCN Content to assist oncology practices.

- NCCN Patient Advocacy Pavilion
  Learn about patient advocacy organizations

- General Poster Session
  View more than 100 posters accepted for the Annual Conference.

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An iMCD Treatment That’s NOW PREFERRED

Siltuximab (SYLVANT®) is now recommended by the National Comprehensive Cancer Network® (NCCN®) as a preferred treatment option for idiopathic multicentric Castleman disease (iMCD) for plasmacytic/mixed histology.¹

Siltuximab continues to be the first-line therapy recommended by the Castleman Disease Collaborative Network (CDCN) guidelines with Category 1 evidence, regardless of histopathologic subtype.²

The only FDA-approved therapy for the treatment of patients with multicentric Castleman disease (MCD) who are negative for human immunodeficiency virus (HIV) and human herpesvirus 8 (HHV-8).³

Limitations of use: SYLVANT was not studied in patients with MCD who are HIV positive or HHV-8 positive because SYLVANT did not bind to virally produced IL-6 in a nonclinical study.³

Please see Important Safety Information and a Brief Summary of Prescribing Information on adjacent pages.

Abbreviations: FDA, US Food and Drug Administration; IL-6, interleukin 6.

SYLVANT® (siltuximab) BRIEF SUMMARY OF PRESCRIBING INFORMATION

CONTRAINDICATIONS
Severe hypersensitivity reaction to siltuximab or any of the excipients in SYLVANT. Hypersensitivity reactions, including anaphylactic reaction, hypersensitivity, and drug hypersensitivity have been reported in patients treated with siltuximab.

WARNINGS AND PRECAUTIONS

Concurrent Active Severe Infections
Do not administer SYLVANT to patients with severe infections until the infection resolves. SYLVANT may mask signs and symptoms of acute inflammation including suppression of fever and of acute Phase reactants such as C-reactive protein (CRP). Monitor patients receiving SYLVANT closely for infections. Institute prompt anti-infective therapy and do not administer further SYLVANT until the infection resolves.

Vaccinations
Do not administer live vaccines to patients or infants born to patients receiving SYLVANT because IL-6 inhibition may interfere with the normal immune response to new antigens.

Infusion Related Reactions and Hypersensitivity
SYLVANT may cause infusion related reactions and anaphylaxis. Symptoms of infusion reactions consisted of back pain, chest pain or discomfort, nausea and vomiting, flushing, erythema, and palpitations. Stop the infusion of SYLVANT if the patient develops signs of anaphylaxis. Discontinue further therapy with SYLVANT.

Gastrointestinal Perforation
Gastrointestinal (GI) perforation has been reported in clinical trials although not in MCD trials. Use with caution in patients who may be at increased risk for GI perforation. Promptly evaluate patients presenting with symptoms that may be associated or suggestive of GI perforation.

ADVERSE REACTIONS

Clinical Trials Experience
Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in clinical practice.

Study 1, in MCD, was an international, multicenter, randomized Phase 2 study of every 3 week infusions comparing SYLVANT and best supportive care (BSC) to placebo and BSC. The patients randomized to SYLVANT (n=53) received a median of 19 infusions (range 1 to 50) compared to patients randomized to placebo (n=26) who received a median of 8 infusions (range 2 to 32). To control for disparate exposure between arms, patient incidence of adverse reactions that occurred during the first 8 infusions are reported.

The most common adverse reactions (>10%) during treatment with SYLVANT and BSC vs placebo vs BSC in the MCD clinical trial were rash (28% vs 12%), pruritus (28% vs 8%), upper respiratory tract infection (26% vs 15%), edema (generalized and local (26% vs 27%), hyperuricemia (11% vs 0%), and increased weight (19% vs 0%).

Study 2 was an open label, long term extension study of patients with MCD treated on prior trials. The median duration of siltuximab treatment was 5.52 years (range: 0.8 to 10.8 years); more than 50% of patients received siltuximab treatment for ≥5 years. The rate of serious or Grade ≥3 adverse events did not increase over time as a function of cumulative exposure.

Other important adverse reactions reported in MCD clinical studies, all of which were very common, were nasopharyngitis, urinary tract infection, neutropenia, dizziness, hypertension, nausea, abdominal pain, vomiting, diarrhea, gastroesophageal reflux disease, mouth ulceration.

Immunogenicity
A total of 432 patients across the clinical studies were evaluated at multiple time points for anti-therapeutic antibody (ATA) responses to siltuximab after treatment with SYLVANT. None of these patients had neutralizing antibodies. The clinical significance of anti-siltuximab antibodies following treatment with SYLVANT is not known.

DRUG INTERACTIONS
Cytochrome P450 Substrates
Inhibition of IL-6 signaling in patients treated with SYLVANT may restore CYP450 activities to higher levels leading to increased metabolism of drugs that are CYP450 substrates compared to metabolism prior to treatment with SYLVANT.

Upon initiation or discontinuation of SYLVANT in patients being treated with CYP450 substrates with a narrow therapeutic index, perform therapeutic monitoring of effect (e.g., warfarin) or drug concentration (e.g., cyclosporine or theophylline) as needed and adjust dose. The effect of SYLVANT on CYP450 enzyme activity can persist for several weeks after stopping therapy. Exercise caution when SYLVANT is co-administered with CYP3A4 substrate drugs where a decrease in effectiveness would be undesirable (e.g., oral contraceptives, lovastatin, atorvastatin).

USE IN SPECIFIC POPULATIONS

Pregnancy
Monoclonal antibodies are transported across the placenta as pregnancy progresses, with the largest amount transferred during the third trimester. Infants born to pregnant women treated with SYLVANT may be at increased risk of infection. Consider the risks and benefits of administering live or live-attenuated vaccines to infants exposed to SYLVANT in utero.

Lactation
Because of the potential for serious adverse reactions in the breastfed child including gastrointestinal perforations, advise patients that breastfeeding is not recommended during treatment with SYLVANT, and for 3 months after the last dose.

Females and Males of Reproductive Potential
SYLVANT may cause embryo-fetal harm when administered to pregnant women. Advise female patients of reproductive potential to use effective contraception during treatment with SYLVANT and for 3 months after the last dose.

Pediatric Use
The safety and efficacy of SYLVANT have not been established in pediatric patients.

Geriatric Use
No differences in the safety profile between the elderly and younger patients were identified, but greater sensitivity of some older individuals cannot be ruled out.

Patients with Renal Impairment
Based on a population pharmacokinetic analysis using data from clinical trials in patients, no significant difference in siltuximab clearance was observed in patients with pre-existing renal impairment (creatinine clearance (CLCr) ≥ 15 mL/min) compared to patients with baseline normal renal function (CLCr ≥ 90 mL/min).

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Stop the infusion if the patient develops a mild to moderate infusion reaction. If the reaction resolves, the SYLVANT infusion may be restarted at a lower infusion rate. Consider medication with antihistamines, acetaminophen, and corticosteroids. Discontinue SYLVANT if the patient does not tolerate the infusion following these interventions.

Administer SYLVANT in a setting that provides resuscitation equipment, medication, and personnel trained to provide resuscitation.

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## NCCN Virtual Reimbursement Resource Room
Reimbursement help and services available to patients with cancer navigating the oncology landscape.

NCCN.org/reimbursement
Questions about Cancer?

NCCN Guidelines for Patients® provide expert cancer treatment information.

Cancer Type
Acute Lymphoblastic Leukemia
Acute Myeloid Leukemia
Bladder Cancer
Brain Cancer/Gliomas
Breast Cancer: Ductal Carcinoma In Situ Invasive Metastatic
Chronic Lymphocytic Leukemia
Chronic Myeloid Leukemia
Colon Cancer
Esophageal Cancer
Head and Neck Cancers: Nasopharyngeal Cancer Oral Cancers Oropharyngeal Cancer
Hepatobiliary Cancers: Liver, Gallbladder, and Bile Duct Cancers
Hodgkin Lymphoma
Kidney Cancer
Lung Cancer: Early and Locally Advanced Metastatic
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Neuroendocrine Tumors
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Ovarian Cancer
Pancreatic Cancer
Prostate Cancer
Rectal Cancer
Soft Tissue Sarcoma
Squamous Cell Skin Cancer
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Nausea and Vomiting
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Adolescents and Young Adults (AYAs) with Cancer
Language Translations
Breast Cancer: Noninvasive Invasive Metastatic
Colon Cancer
Kidney Cancer
Lung Cancer: Early and Locally Advanced Metastatic
Ovarian Cancer
Stomach Cancer

NCCN Patient Guides for Cancer
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NATIONAL COMPREHENSIVE CANCER NETWORK
Guiding Treatment, Changing Lives,
Seeking answers to some of the most challenging questions in cancer research

**Cancer Epigenetics**
- How can we target specific epigenetic pathways to treat cancer?
- What epigenetic changes drive cancer development and progression?

**Onco-immunology**
- How can we harness the body’s own immune system to attack cancer?
- Which drugs, alone or in combination, have the greatest potential to reduce treatment resistance and provide the most durable response?

**Onco-therapy**
- Can a patient’s own immune cells be modified with redirected specificity to treat their cancer?
- Which targeted receptors have the most potential impact on tumor cells?

**Synthetic Lethality**
- Which pathways are required for detection, repair, and bypass of DNA damage in cancer cells?
- How can we interfere with maladaptive DNA repair processes to inhibit tumor growth?

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Patient Advocacy Pavilion
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BAG IT
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Colorectal Cancer Alliance
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International Waldenstrom’s Macroglobulinemia Foundation (IWMF)
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LUNGevity Foundation
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NTD TV
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PALTOWN Development Foundation
Patient Empowerment Network (PEN)
Sharsheret
Triage Cancer

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NCCN Apps for the Oncology Community

Virtual Library of NCCN Guidelines®
This easy-to-use and convenient format further assists health care professionals in their implementation of the NCCN Guidelines® and NCCN Guidelines for Patients®, thus improving care provided to people with cancer.

- Easy access to NCCN Guidelines, global resources, and NCCN Guidelines for Patients
- Hyperlinks within the Guidelines
- Ability to quickly share Guidelines
- Optimized search and viewing options

NCCN Patient Guides for Cancer
People with cancer and caregivers can access patient-friendly NCCN Guidelines for expert cancer treatment information.

- Step-by-step guides to treatment options
- Questions to ask doctors
- Patient-friendly illustrations
- Based on information doctors use
- Ability to download and share patient guidelines

NCCN Reimbursement Resource
The cost of cancer care continues to rise and patients with cancer and their caregivers often struggle to pay for therapy. Search for available resources and payment assistance programs by:

- Cancer type or supportive care indication
- Drug name
- Company/program name

Visit NCCN.org/apps
or download through the app store on your mobile device.
Biologics are unique and complex molecules and biosimilars are highly similar to the reference biologic.¹

Teva has a legacy of value-based generics and branded products. Teva is committed to being a leader in biosimilars, with a growing portfolio and a deep pipeline of biosimilar medicines.


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The Anal Cancer Foundation

empowers anal cancer patients and accelerates prevention and treatment methods to eliminate anal cancer and the virus that causes the majority of cases, HPV.

The Foundation started in 2010 when three siblings, Justine, Tristan and Camille Almada, lost their wonderful mother Paulette to stage IV HPV-related anal cancer. When Paulette was diagnosed at the age of 51, her treatment options were the same as existed in 1974 and there were few medical or support resources for her to fight the disease. Since its founding, the organization has become a leader in the fight against anal cancer and HPV, which causes 5% of all cancers.

The Anal Cancer Foundation has achieved key milestones towards eradicating anal cancer and supporting patients including:

- Investing hundreds of thousands of dollars in novel scientific research for new treatments. In 2018, treatment guidelines were updated with a Foundation-funded immunotherapy that provides the first advance in metastatic anal cancer treatment in four decades.
- Establishing the first scientific medical society and network for anal cancer.
- Leading coalitions of disease and medical groups to ensure equal access to the cancer-preventing HPV vaccine.
- Creating the first educational forums and peer support program for anal cancer patients and caregivers.
- Educating clinicians about best practices to improve the anal cancer patient experience.

Please visit our website for the latest medical news on HPV and anal cancer. It is also a great support system for patients and their families. www.analcancerfoundation.org

Anal Cancer Foundation | @hpvanalcancer
PO Box 232 · New York, NY 10272 · +1 646-593-7739
3 Albert Mews, Albert Road · London, N4 3RD UK · +44 20-7272 3347

ACF ANAL CANCER FOUNDATION
What’s in the bag:
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• A customizable My Companion Guidebook that helps patients organize and access their medical information

What the bag means to your practice:
• Saves time and costs by compiling resources into a single toolkit
• Helps practices meet accreditation guidelines
• Improves patient adherence to treatment and supports better outcomes

Patient education focusing on self-advocacy and survivorship through the continuum of care

SPECTRUM IS COMMITTED TO THE FIGHT AGAINST CANCER

Our passion to identify, develop and deliver options for patients with cancer is behind every action we take.

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CRA Health
CRA Health is breaking down barriers in the identification and management of patients at high-risk for breast cancer across many care settings. With over 15 years providing risk assessment, we now help care for 2,000,000 patients annually. We provide a comprehensive and targeted assessment that reflects your clinical objectives delivered with core strengths for EHR, Density/AI, and laboratory systems integration. Elevate the standard of care for your patients with our high-quality risk assessment program.

CureMD
CureMD Oncology is the leading All-in-One EHR, Practice Management and Billing Services solution that provides NCCN Template library powered chemotherapy ordering, with links to NCCN Guidelines. It features decision support systems for dose calculations, medication administration record, automatic charge capture, clearing house, mobile-EMR and Check-in KIOSK. Our ASCO CancerLinQ® integration provides important clinical quality insights leading to improved outcomes. Learn more @www.curemd.com/ oncology/ to find out why CureMD is the premier choice for Hematology-Oncology practices.

CVS Specialty
Our commitment to helping patients and their physicians manage complex drug therapies by delivering expert individualized care and unmatched, multi-channel access has made us one of the leading specialty pharmacies in the country. We provide a full-range of pharmaceutical care, dispensing the latest FDA-approved medications.

Equicare Health
Equicare Health is the industry’s leading provider of comprehensive care coordination solutions. EQUICARE CS™ is a web-based software tool that facilitates patient engagement including patient reported outcomes, patient navigation, survivorship care and other clinical tools like MDT, clinical trials, etc. Equicare offers an administrative suite of worklists and reports for managing adherence to many accreditation standards. ECS enables cancer centers to influence clinical outcomes for patients, optimize revenue streams and increase operational efficiency.

Flatiron Health
Flatiron Health is a healthcare technology and services company focused on accelerating cancer research and improving patient care. Our platform enables cancer researchers and care providers to learn from the experience of every patient. Currently, Flatiron partners with over 280 community cancer practices, seven major academic research center, and over 15 of the top therapeutic oncology companies. For more information, please visit www.flatiron.com or follow us @FlatironHealth.

McKesson
At McKesson, we clear the path so you can care for your patients. The health of your specialty practice goes beyond pharmaceutical distribution, and so does our support. We work with you to understand your entire business and offer ways to achieve your unique goals. We enable you to run your practice your way while increasing your efficiency, reimbursement and time for patient care. Our broad portfolio of provider solutions and services can’t be matched.

Navigating Cancer
Navigating Cancer is the leader in patient relationship management software for cancer care. This patient-centered oncology platform puts the patient at the center of their own care and enables the care team to provide coordinated and comprehensive care at a lower cost. The platform enables providers to gain efficiencies in their care, meet value-based care initiatives, improve medication adherence and reduce hospitalizations for cancer patients.

Optum
Optum Cancer Guidance Program (CGP) is an evidence-based cancer treatment, utilization management and analytics service to help Payers and Employers reduce the medical expenses associated with a range of high cost, complex cancer treatments. This comprehensive solution includes an online portal that helps providers obtain authorizations quickly and easily. It also provides extensive analytics and reporting to encourage better decision making.

Outcomes4Me Inc.
Outcomes4Me is on a mission to improve health outcomes by providing a personalized, expert-validated evidence-based experience for patients. By delivering a complete view of their personal clinical information and up-to-date, clinically-validated treatment options, the Outcomes4Me platform empowers patients with their own care facilitating informed decision making and care management. Our technology-based solution combines patient input with clinical data to generate the real-world evidence necessary to drive future clinical decisions and improve outcomes.

PatientPoint
PatientPoint® is a patient engagement solutions company passionately committed to making every doctor-patient engagement better™. Learn more at www.patientpoint.com.

Roche Diagnostics Corporation - NAVIFY
Decision Support Portfolio
As the world’s largest biotech company, Roche is focused on advancing science to improve people’s lives. The NAVIFY clinical decision support platform helps multi-disciplinary care teams navigate increasingly complex medical information and empowers them with holistic and actionable data. The first commercially available product in the portfolio is NAVIFY Tumor Board, a cloud-based software solution that changes the way oncology care teams prepare for conduct and document clinical treatment decisions.

Siemens Healthineers
Siemens Healthineers offers products and services in the areas of diagnostic and therapeutic imaging, laboratory diagnostics, molecular medicine, digital health services and enterprise services. Our solution Al-Pathway Companion leverages data integration and artificial intelligence to support multidisciplinary teams to ease diagnosis and treatment decisions and may enable personalized and standardized patient management and plans to offer process improvement insights through analysis of key performance indicators supporting patient-centric diagnosis and treatment decisions along disease-specific care pathways.

Varian Medical Systems
Imagine a world free from the fear of cancer. We do, every day. That’s why at Varian, we’re obsessed with creating simpler, more efficient, and more effective technologies to power new victories in cancer care. Varian is the long-standing global leader in comprehensive solutions for radiotherapy and radiosurgery, as well as software systems for managing cancer clinics, sharing knowledge and using data to deliver evidence-based care.
Patient Advocacy Pavilion

Anal Cancer Foundation
The Anal Cancer Foundation is a donor-supported research, support and advocacy non-profit organization. The Foundation empowers anal cancer patients and accelerates prevention and treatment methods to eliminate anal cancer and the virus that causes it and other cancers, HPV.

BAG IT
Bag It is a patient education resource focusing on self-advocacy and survivorship. It contains a customizable binder (My Companion Guidebook) to help patients organize, navigate and access their medical information. There is reliable printed information on a variety of critical topics from national cancer organizations. The bag, available in both English and Spanish, helps patients and their families have the knowledge and confidence to be their own best advocate for their best quality of life.

Cancer Hope Network
Cancer Hope Network provides free one-on-one emotional support to adult cancer patients and their loved ones. Each of CHN’s 400+ volunteers is at least one year post-treatment or successfully undergoing maintenance therapies. They have faced more than 80 cancer types and speak 15 languages. Our volunteers offer support from diagnosis, through treatment and into recovery. Each match is overseen by our professional Programs Team. CHN serves clients in the United States and Canada.

Colon Cancer Foundation
The Colon Cancer Foundation – Our vision is A World Without Colorectal Cancer™. Our mission is to lead the fight against colorectal cancer (CRC) by promoting prevention through community awareness and education, leading advocacy efforts focused on improving the quality of life of patients, their families and caregivers and supporting colon and rectal cancer research initiatives.

Colorectal Cancer Alliance
Colorectal Cancer Alliance is a national non-profit committed to ending colorectal cancer within our lifetime. We empower a nation of passionate survivors and advocates to help patients and caregivers navigate diagnosis and treatment, and we serve as allies with healthcare professionals—those who understand the value of early detection. Partnering with doctors and nurses around the country, we are working urgently to raise awareness of preventive screening because we believe tomorrow can’t wait. #tomorrowwantswhat #onationofallies ccalliance.org

Fight Colorectal Cancer
The leading patient advocacy organization focused on providing patient education, impactful policy change, and research endeavors.

International Myeloma Foundation (IMF)
The International Myeloma Foundation (IMF) is dedicated to improving the quality of life of myeloma patients while working toward prevention and a cure through our 4 founding principles: Research, Education, Support, and Advocacy.

International Waldenstrom's Macroglobulinemia Foundation (IWMF)
The International Waldenstrom's Macroglobulinemia Foundation (IWMF) is a patient-founded and volunteer-led nonprofit organization dedicated to a simple but compelling mission: Support and education everyone affected by Waldenstrom's Macroglobulinemia (WM) while advancing the search for a cure.

Kidney Cancer Association
The Kidney Cancer Association is a global community dedicated to serving and empowering patients and leading change through advocacy, research, and education in order to be the universal leader in the cure for kidney cancer.

The Leukemia & Lymphoma Society
The Leukemia & Lymphoma Society (LLS) is the world’s largest voluntary health agency dedicated to blood cancer. The LLS mission: Cure leukemia, lymphoma, Hodgkin’s disease and myeloma, and improve the quality of life of patients and their families. LLS funds lifesaving blood cancer research around the world and provides free information and support services. www.LLS.org/PatientSupport.

LUNGevity Foundation
LUNGevity Foundation is firmly committed to making an immediate impact on increasing quality of life and survivorship of people with lung cancer by accelerating research into early detection and more effective treatments, as well as providing community, support, and education for all those affected by the disease.

Lymphoma Research Foundation
The Lymphoma Research Foundation’s mission is to eradicate lymphoma and serve those impacted by this blood cancer.

Nicki Leach Foundation
The mission of the Nicki Leach Foundation is to honor Nicki’s request and help young adults, (AYA’s) who have cancer so they can continue their educational dreams and goals, we do this through endowed scholarships for their education. We also help fund cancer research involving Adolescents & Young Adults between the ages of 18-39 hoping to find better treatments and cures. Nicki lost her life to cancer (glioblastoma) brain tumor at 19.

NTD TV (New Tang Dynasty Television)
NTD is a 501c(3) TV broadcaster founded in 2001. Headquartered in New York City, NTD is committed to helping new immigrants integrate into American society and to help to address the growing need from the Chinese and Asian immigrants’ community to access health and medical information.

OneClickFund.com
Patients First. OneClickFund.com provides support for patients and caregivers and funding for kidney cancer research.

PALTOWN Development Foundation
GROWING Patient-Powered Disease-Specific Communities. TRAINING & EMPOWERING Patient Leaders.

Patient Empowerment Network (PEN)
Patient Empowerment Network’s (PEN) mission is to fortify cancer patients and care partners with knowledge and tools to boost their confidence, put them in control of their healthcare journey, and assist them with receiving the best, most personalized care available. Our programs focus on enhancing health literacy to enable shared decision-making and providing information and educational resources to help patients consider clinical trials as an option throughout treatment.

Sharsheret
Sharsheret is a national not-for-profit organization that provides free psychosocial support to women facing breast and ovarian cancers or genetic mutations that raise diagnostic risk. Sharsheret also provides free cultural competency training to staff of cancer centers throughout the country. For more information or to learn about how our programs and help your patients, visit us at www.sharsheret.org or call us at (866) 474-2774.

Triage Cancer
Triage Cancer is a national, nonprofit organization that provides education on the practical and legal issues that may impact individuals diagnosed with cancer and their caregivers, through events, quick guides, and cancer resources.
About Our Exhibitors

AbbVie
At AbbVie, we strive to discover and develop medicines that deliver transformational improvements in cancer treatment by uniquely combining our deep knowledge in core areas of biology with cutting-edge technologies, and by working together with our partners – scientists, clinical experts, industry peers, advocates, and patients. We remain focused on delivering these transformative advances in treatment across some of the most debilitating and widespread cancers. We are also committed to exploring solutions to help patients obtain access to our cancer medicines. AbbVie’s oncology portfolio now consists of marketed medicines and a pipeline containing multiple new molecules being evaluated worldwide in more than 300 clinical trials and more than 20 different tumor types. For more information, please visit www.abbvie.com/oncology.

Astellas Pharma US Inc.
Astellas Pharma US Inc. is a U.S. affiliate of Astellas Pharma, a global pharmaceutical company that delivers innovative and improving the health of people around the world through the provision of innovative and reliable pharmaceutical products.

AstraZeneca
AstraZeneca is a global, science-led biopharmaceutical company that focuses on the discovery, development and commercialization of prescription medicines, primarily for the treatment of diseases in three therapy areas – Oncology, Cardiovascular, Renal & Metabolism and Respiratory. For more information, please visit www.astrazeneca-us.com and follow us on Twitter @AstraZenecaUS.

Athenex Oncology
Athenex is a global biopharmaceutical company dedicated to the discovery, development, and commercialization of novel therapies to treat cancer. Our mission is to improve the lives of cancer patients by creating more effective, safer, and tolerable treatments. Our clinical pipeline drugs are based on our understanding of human absorption biology and novel approaches to inhibiting kinase activity. Our ability to overcome the challenges of oral delivery of chemotherapy and convert cornerstone therapies to the oral route offers significant potential benefits to patient outcomes.

Daiichi Sankyo, Inc.
Daiichi Sankyo, Inc., headquartered in Basking Ridge, New Jersey, is the U.S. subsidiary of Daiichi Sankyo Co., Ltd. Daiichi Sankyo, Inc. is a member of the Daiichi Sankyo Group and is focused on the development of oncology therapies and specialty medicines. Daiichi Sankyo, Inc. medicines approved in the U.S. include therapies for hypertension, pain management, dyslipidemia, diabetes, thrombosis, stroke risk reduction, acute coronary syndrome, opioid-induced constipation, IV iron therapy and metastatic melanoma.

Dendreon
Dendreon is a commercial-stage biopharmaceutical company and pioneer in the development of treatments that harness the power of the immune system to extend life. Dendreon's flagship product, PROVENGE® (sipuleucel-T), was the first FDA-approved immunotherapy made from a patient's own immune cells. Nearly 40,000 men with advanced prostate cancer have been prescribed PROVENGE in the U.S. since 2010. Dendreon also is evaluating the use of PROVENGE in early-stage prostate cancer, with the hope of curing more men of the disease. Dendreon is headquartered in Seal Beach, Calif. For more information, please visit www.dendreon.com.

Eisai Inc.
As the U.S. pharmaceutical subsidiary of Tokyo-based Eisai Co., Ltd., our passionate commitment to patient care is the driving force behind our efforts to help address unmet medical needs. We are a fully integrated pharmaceutical business with discovery, clinical, and marketing capabilities. Our key areas of focus include oncology and neurology (dementia-related diseases and neurodegenerative diseases). To learn more about Eisai Inc., please visit us a www.eisai.com/US and follow us on Twitter and LinkedIn.

EUSA Pharma
EUSA Pharma is a dynamic, global biopharmaceutical company focused on oncology and rare disease, continuously striving to confront gaps in patient care. Our ambition drives us to deliver medical treatments that deliver real change to improve lives wherever they are needed in the world. As a young, specialty pharmaceutical company, EUSA Pharma is committed to delivering solutions that can have a meaningful effect on life, helping patients across a range of therapy areas. www.eusapharma.com

Exelixis, Inc.
Founded in 1994, Exelixis, Inc. (Nasdaq: EXEL) is a commercially successful, oncology-focused biotechnology company that strives to accelerate the discovery, development and commercialization of new medicines for difficult-to-treat cancers. We are supplementing our existing therapeutic assets with targeted business development activities and internal drug discovery – all to deliver the next generation of Exelixis medicines and help patients recover stronger and live longer. www.exelixis.com

Ferring Pharmaceuticals Inc.
Ferring Pharmaceuticals is a research-driven biopharmaceutical company devoted to identifying, developing and marketing innovative products in the fields of reproductive medicine, maternal health, urology, gastroenterology, endocrinology, orthopaedics and oncology. For more information, visit www.FerringUSA.com

GSK
GSK is focused on maximizing patient survival through transformational medicines. GSK’s pipeline is focused on immuno-oncology, cell therapy, cancer epigenetics, and synthetic lethality. Our goal is to achieve a sustainable flow of new treatments based on a diversified portfolio of investigational medicines utilizing modalities such as small molecules, antibodies, antibody drug conjugates and cells, either alone or in combination.

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**Platinum Sponsor**

**Incyte Corporation**
Incyte is a global biopharmaceutical company that is focused on finding solutions for serious unmet medical needs through the discovery, development and commercialization of novel medicines. Since 2002, Incyte has remained committed to the relentless pursuit of science that can improve the lives of patients, make a difference in healthcare and build sustainable value for our stakeholders. The Company is advancing a diversified portfolio of clinical candidates across two franchises: Oncology and Inflammation & Autoimmunity. Headquartered in Wilmington, Delaware, Incyte has operations in the U.S., Europe and Japan. For more information, visit Incyte.com and follow @Incyte.

**Ipsen Biopharmaceuticals, Inc.**
Ipsen Biopharmaceuticals, Inc. is a US affiliate of Ipsen SA, a global biotech company. At Ipsen Biopharmaceuticals, we are focused on developing and providing access to therapies across our core therapeutic areas: oncology, neurology and rare diseases, because our mission is to offer options for patients who suffer from these extremely difficult-to-treat diseases. For more information on Ipsen in North America, please visit www.ipensenus.com.

**Gold Sponsor**

**Janssen Biotech, Inc.**
At Janssen, we’re creating a future where disease is a thing of the past. We’re the Pharmaceutical Companies of Johnson & Johnson, working tirelessly to make that future a reality for patients everywhere by fighting sickness with science, improving access with ingenuity, and healing hopelessness with heart. At Janssen Oncology, we’re shaping the future of cancer treatment. And in the process, we’re striving to change expectations of what a cancer diagnosis means. Our purpose is driven by an urgency and commitment to bringing transformational cancer solutions to the people who need them. For more information, visit https://www.janssen.com/oncology.


**Bronze Sponsor**

**Jazz Pharmaceuticals, Inc.**
Jazz Pharmaceuticals plc (Nasdaq: JAZZ), a global biopharmaceutical company, is dedicated to developing life-changing medicines for people with limited or no options, so they can live their lives more fully and redefine what is possible. As a leader in sleep medicine and with a growing hematology/oncology portfolio, Jazz has a diverse portfolio of products and product candidates in development, and is focused on transforming biopharmaceutical discoveries into novel medicines.

**Karyopharm Therapeutics, Inc.**
Karyopharm Therapeutics is an oncology-focused pharmaceutical company dedicated to the discovery, development, and commercialization of novel first-in-class drugs for the treatment of cancer and other major diseases. Karyopharm’s lead compound, XPOVIO™ (selinexor), received accelerated approval from the FDA in combination with dexamethasone as a treatment for patients with heavily pretreated multiple myeloma.

**Kite, A Gilead Company**
Kite, a Gilead Company, is a biopharmaceutical company based in Santa Monica, California. Kite is engaged in the development of innovative cancer immunotherapies. The company is focused on chimeric antigen receptor and T cell receptor engineered cell therapies. For more information on Kite, please visit www.kitepharma.com.

**Merck & Co., Inc.**
For more than a century, Merck has been inventing for life, bringing forward medicines and vaccines for many of the world’s most challenging diseases. Today, Merck continues to be at the forefront of research to deliver innovative health solutions and advance the prevention and treatment of diseases around the world.

**Natera**
Natera has developed Signatera, a personalized ctDNA test for molecular residual disease (MRD) detection and recurrence monitoring in patients previously diagnosed with cancer. Signatera’s tumor-informed assay is optimized to detect low levels of ctDNA, with high accuracy in identifying MRD and recurrence with longer lead times. Signatera has been clinically validated in multiple cancer types including colorectal, non-small cell lung, breast, and bladder cancers. Learn more at natera.com/oncology.

**Novocure Inc.**
Novocure is an oncology company developing a profoundly different cancer treatment utilizing a proprietary therapy called TTFields, the use of electric fields tuned to specific frequencies to disrupt solid tumor cancer cell division.

**Ontology Nutrition Dietetic Practice Group**
Ontology Nutrition Dietetic Practice Group (ON DPG) of the Academy of Nutrition and Dietetics promotes excellence in oncology dietetic practice, education, and research through advocacy, publications, symposiums, and webinars. Attendees will be offered education materials on screening and diagnosing malnutrition -since up to 80% of cancer patients are malnourished at some point during their cancer care- and information regarding the vital role of a Registered Dietitian Nutritionist (RDN) on the health care team.

**Pacific Edge Diagnostics**
Pacific Edge is a cancer diagnostics company specializing in bladder cancer diagnostic technology. Cxbladder is a non-invasive, clinically validated laboratory test that measures the gene expression levels of five biomarkers that represent a bladder cancer signature. With three different tests, Cxbladder is optimized for the detection or rule out of bladder cancer across the entire patient continuum.

**Pfizer**
At Pfizer Oncology, we are committed to advancing medicines wherever we believe we can make a meaningful difference in the lives of patients. Today, Pfizer Oncology has an industry-leading portfolio of 22 approved innovative cancer medicines and biosimilars across more than 30 indications, including breast, prostate, kidney and lung cancers, as well as leukemia and melanoma.

**Silver Sponsor**

**Regeneron**
Regeneron Pharmaceuticals is a leading biotechnology company that invents life-transforming medicines for people with serious diseases. Sanofi is dedicated to supporting people through their health challenges. We are a global biopharmaceutical company focused on human health. Since 2007, Sanofi & Regeneron have collaborated to develop & commercialize fully human monoclonal antibodies utilizing proprietary technologies.

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About Our Exhibitors

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Sanofi Genzyme
Sanofi Genzyme, the specialty care global business unit of Sanofi, focuses on rare diseases, multiple sclerosis, oncology, and immunology. We help people with debilitating and complex conditions that are often difficult to diagnose and treat. Our approach is shaped by our experience developing highly specialized treatments and forging close relationships with physician and patient communities. We are dedicated to discovering and advancing new therapies, providing hope to patients and their families around the world. Learn more at www.sanofigenzyme.com.

Seattle Genetics
Seattle Genetics, Inc. is a global biotechnology company that discovers, develops, and commercializes transformative medicines targeting cancer to make a meaningful difference in people's lives. ADCETRIS® (brentuximab vedotin) and PADCEV™ (enfortumab vedotin-efv) use the company's industry-leading antibody-drug conjugate (ADC) technology. ADCETRIS is approved in certain CD30-expressing lymphomas, and PADCEV is approved in certain metastatic urothelial cancers. TUKYSA™ (tucatinib) is a small molecule tyrosine kinase inhibitor and is approved for certain HER2-positive metastatic breast cancers. For more information, visit www.seattlegenetics.com and follow @SeattleGenetics on Twitter.

Spectrum Pharmaceuticals, Inc.
Spectrum Pharmaceuticals is a biopharmaceutical company focused on acquiring, developing, and commercializing novel and targeted oncology therapies. Spectrum has a strong track record of successfully executing across the biopharmaceutical business model, from in-licensing and acquiring differentiated drugs, clinically developing novel assets, successfully gaining regulatory approvals and commercializing in a competitive healthcare marketplace. Spectrum has a late-stage pipeline with novel assets that serve areas of unmet need. For additional information visit www.sppirx.com.

Taiho Oncology
Taiho Oncology, Inc., a subsidiary of Taiho Pharmaceutical Co., Ltd. and Otsuka Holdings Co., Ltd., has established world-class clinical development and commercial organizations that work urgently to develop and market innovative cancer treatments in the U.S. Taiho Oncology Inc. has an oral oncology pipeline consisting of both novel antimetabolic agents and selectively targeted agents. Advanced technology, dedicated researchers, and state-of-the-art facilities are helping us to define the way the world treats cancer. It’s our work; it’s our passion; it’s our legacy.

Takeda
At Takeda Oncology, we endeavor to deliver novel medicines to patients with cancer worldwide through our commitment to science, breakthrough innovation and passion for improving the lives of patients. This singular focus drives our aspirations to discover, develop and deliver breakthrough oncology therapies. By concentrating the power of leading scientific minds and the vast resources of a global pharmaceutical company, we are finding innovative ways to improve the treatment of cancer. We know that our mission is not a quick or simple one, but we are up for the task: we aspire to cure cancer. www.takedaoncology.com

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Teva Pharmaceutical Industries Ltd.
Teva Pharmaceutical Industries Ltd. is a global leader in generic medicines and biopharmaceuticals. Building on more than a century-old legacy, Teva delivers high-quality products to patients in nearly every therapeutic area, has an established presence in generics, specialty, OTC and API, a fully integrated R&D function, strong operational base and global infrastructure and scale.

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View more than 100 posters accepted for the 2020 Annual Conference.

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Your patients with lung cancer have questions. We can help.

LUNGevity has information and support that patients and caregivers need to make informed healthcare decisions. Visit www.LUNGevity.org to learn more.

Lung Cancer 101 is a comprehensive medically vetted online guide to understanding how lung cancer develops, how it can be detected, treatment options and what to expect. Download tips, booklets, and informational videos.

Experts Blog includes clear discussions about the latest developments in research and what they mean for patients.

Lung Cancer Navigator mobile app helps patients manage their healthcare. Lung Cancer HELPLine is a toll-free support service answered by oncology social workers. Call 844-360-LUNG.

Online Survivor and Caregiver Resource Centers help patients live well with lung cancer, and provide tip sheets with questions for visits with one’s medical team.

PEER-TO-PEER SUPPORT

Lifeline matches patients and caregivers to mentors who have had similar experiences, for personalized one-on-one support.

Clinical Trial Ambassadors are volunteers available to offer information about their personal experiences with clinical trials to fellow lung cancer patients.

Lung Cancer Support Community message boards provide patients and caregivers with peer-to-peer support and information.

The International Lung Cancer Survivorship Conference is a unique, weekend conference, designed by and for people diagnosed with lung cancer and their caregivers. The conference teaches attendees how to live well at all stages of a lung cancer diagnosis.

About LUNGevity Foundation

LUNGevity Foundation is firmly committed to making an immediate impact on increasing quality of life and survivorship of people with lung cancer by accelerating research into early detection and more effective treatments, as well as by providing community, support, and education for all those affected by the disease. For more information, please visit www.LUNGevity.org.
Colorectal cancer is the second-leading cause of cancer-related deaths in the U.S.

**We are a nation of passionate allies determined to end this senseless killer.**

Join us at [NationOfAllies.org](http://NationOfAllies.org)

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**Our vision:**

A World without WM (Waldenstrom's macroglobulinemia).

**Our mission:**

Support and educate everyone affected by Waldenstrom's macroglobulinemia (WM) while advancing the search for a cure.

[WWW.IWMF.COM](http://WWW.IWMF.COM)

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NCCN EXHIBITION GUIDE - 25

KNOWLEDGE IS YOUR SUPERPOWER!

BUT WHERE DO YOU BEGIN?

Start with the Patient Empowerment Network, a non-profit, dedicated to giving cancer patients the knowledge and tools to:

- Boost your confidence,
- Put you in control of your healthcare journey
- Assist you in receiving the best, most personalized care

Our programs and resources are free to participants thanks to the support of our partners and donors.

Easily access medical experts, industry leaders, peers, patients, advocates, and curated resources addressing a broad range of topics.

Our Path to Empowerment empowers and educates you through each stage in the cancer journey, from the first office visit and testing, through life after treatment.

Sign up for our newsletter and follow us on social media for the latest in cancer developments, inspiring patient stories and easy-to-understand information for patients and care partners.

powerfulpatients.org @power4patients

We are supporting Adolescents & Young Adults (AYAs) with cancer, through research and endowed grants for education

“Nicki always found beauty in the world even in the worst of circumstances. When she knew her life here was ending, she gave me an assignment. She asked me to find a way to help others like I helped her. Nicki never stopped smiling.” - Bunny Leach

The mission of the Nicki Leach Foundation is to honor Nicki’s request to find a way to help young adults who have cancer. Nicki lost her life to cancer at 19.

We fund cancer research involving Adolescents & Young Adults (AYAs) between the ages of 15-39 who have cancer. In addition, the Nicki Leach Foundation helps provide endowed grants to support their educational goals. We see this as an unmet need.

Thank you for supporting our mission so that we can help AYAs achieve their educational goals and continue our efforts to find new treatments leading to cures for AYA cancers.

The Nicki Leach Foundation is a public nonprofit 501(c)(3) Corporation. We depend on your support.

The Nicki Leach Foundation
190 Coastal Oak Circle
Ponte Vedra Beach, FL 32082
(904) 716-5394
www.nickileach.org
For nearly forty years, Cancer Hope Network Support Volunteers like those pictured above have been providing free and confidential one-on-one emotional peer support to adult cancer patients and their loved ones.

Each of our 400+ Support Volunteers is at least one year post-treatment or successfully undergoing maintenance therapies. They have faced more than 80 cancer types and speak 15 languages. They offer encouragement from diagnosis, through treatment and into survivorship.

For more information or to learn how we can support your patients and their caregivers, come see us in the Exhibit Hall, visit cancerhopenetwork.org or call 877-HOPENET.

877-HOPENET
CANCERHOPENETWORK.ORG

NTD provides Asian patients with in-language disease education through TV, print, digital, social and live events

- Nonprofit TV broadcaster
- Connection to Asian patients and physicians
- Dedication to public health and patient advocacy in the Asian community in US
- Multi-language services: Chinese, Korean, Vietnamese, Japanese and English

Visit our booth or email us at: health@ntdtv.com
Visit the International Myeloma Foundation (IMF) at the National Comprehensive Cancer Network annual conference at: **Kiosk A16** (Located in the Patient Advocacy Pavilion)

The IMF is dedicated to improving the quality of life of myeloma patients while working toward prevention and a cure through our four founding principles: Research, Education, Support, and Advocacy.
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• Hereditary Breast and Ovarian Cancers in the Jewish Community
• Coping with Cancer: A New Approach to Reduce Cancer-Related Stress in Patients
We can create additional trainings based on the specific needs of your health care team.

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Unstoppable Together.

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IN THE MARATHON OF MYELOMA TREATMENT, ARE YOU DROPPING THE PROTEASOME INHIBITOR TOO SOON?

Continuous treatment with a proteasome inhibitor (PI)-based regimen is associated with clinical benefits, including for patients with high-risk cytogenetics. However, many patients who have had 1 prior therapy receive injectable PIs for only 4 to 7 months.²,³

The NINLARO® (ixazomib) regimen extended median PFS by ~6 months (median: 20.6 vs 14.7 months) vs the placebo regimen in patients with multiple myeloma who have received at least 1 prior therapy.¹

Consider prescribing the all-oral NINLARO regimen for long-term proteasome inhibition.

TOURMALINE-MM1: a global, phase 3, randomized (1:1), double-blind, placebo-controlled study that evaluated the safety and efficacy of NINLARO (an oral PI) vs placebo, both in combination with lenalidomide and dexamethasone, until disease progression or unacceptable toxicity in 722 patients with relapsed and/or refractory multiple myeloma who received 1-3 prior therapies.¹

NINLARO is indicated in combination with lenalidomide and dexamethasone for the treatment of patients with multiple myeloma who have received at least one prior therapy.
IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

• **Thrombocytopenia** has been reported with NINLARO. During treatment, monitor platelet counts at least monthly, and consider more frequent monitoring during the first three cycles. Manage thrombocytopenia with dose modifications and platelet transfusions as per standard medical guidelines. Adjust dosing as needed. Platelet nadirs typically occurred between Days 14-21 of each 28-day cycle and recovered to baseline by the start of the next cycle.

• **Gastrointestinal Toxicities**, including diarrhea, constipation, nausea and vomiting, were reported with NINLARO and may occasionally require the use of antidiarrheal and antiemetic medications, and supportive care. Diarrhea resulted in the discontinuation of one or more of the three drugs in 1% of patients in the NINLARO regimen and <1% of patients in the placebo regimen. Adjust dosing for severe symptoms.

• **Peripheral Neuropathy** (predominantly sensory) was reported with NINLARO. The most commonly reported reaction was peripheral sensory neuropathy (19% and 14% in the NINLARO and placebo regimens, respectively). Peripheral motor neuropathy was not commonly reported in either regimen (<1%). Peripheral neuropathy resulted in discontinuation of one or more of the three drugs in 1% of patients in both regimens. Monitor patients for symptoms of peripheral neuropathy and adjust dosing as needed.

• **Peripheral Edema** was reported with NINLARO. Monitor for fluid retention. Investigate for underlying causes when appropriate and provide supportive care as necessary. Adjust dosing of dexamethasone per its prescribing information or NINLARO for Grade 3 or 4 symptoms.

• **Cutaneous Reactions**: Rash, most commonly maculo-papular and macular rash, was reported with NINLARO. Rash resulted in discontinuation of one or more of the three drugs in <1% of patients in both regimens. Manage rash with supportive care or with dose modification.

• **Thrombotic Microangiopathy**: Cases, sometimes fatal, of thrombotic microangiopathy, including thrombotic thrombocytopenic purpura/hemolytic uremic syndrome (TTP/HUS), have been reported in patients who received NINLARO. Monitor for signs and symptoms of TTP/HUS.

If the diagnosis is suspected, stop NINLARO and evaluate. If the diagnosis of TTP/HUS is excluded, consider restarting NINLARO. The safety of restarting NINLARO therapy in patients previously experiencing TTP/HUS is not known.

• **Hepatotoxicity** has been reported with NINLARO. Drug-induced liver injury, hepatocellular injury, hepatic steatosis, hepatitis cholestatic and hepatotoxicity have each been reported in <1% of patients treated with NINLARO. Events of liver impairment have been reported (6% in the NINLARO regimen and 5% in the placebo regimen). Monitor hepatic enzymes regularly during treatment and adjust dosing as needed.

• **Embryo-fetal Toxicity**: NINLARO can cause fetal harm. Women should be advised of the potential risk to a fetus, to avoid becoming pregnant, and to use contraception during treatment and for an additional 90 days after the final dose of NINLARO. Women using hormonal contraceptives should also use a barrier method of contraception.

ADVERSE REACTIONS

The most common adverse reactions (≥20%) in the NINLARO regimen and greater than the placebo regimen, respectively, were diarrhea (42%, 36%), constipation (34%, 25%), thrombocytopenia (78%, 54%; pooled from adverse events and laboratory data), peripheral neuropathy (28%, 21%), nausea (26%, 21%), peripheral edema (25%, 18%), vomiting (22%, 11%), and back pain (21%, 16%). Serious adverse reactions reported in ≥2% of patients included thrombocytopenia (2%) and diarrhea (2%).

DRUG INTERACTIONS: Avoid concomitant administration of NINLARO with strong CYP3A inducers.

SPECIAL POPULATIONS

• **Hepatic Impairment**: Reduce the NINLARO starting dose to 3 mg in patients with moderate or severe hepatic impairment.

• **Renal Impairment**: Reduce the NINLARO starting dose to 3 mg in patients with severe renal impairment or end-stage renal disease requiring dialysis. NINLARO is not dialyzable.

• **Lactation**: Advise nursing women not to breastfeed during treatment with NINLARO and for 90 days after the last dose.

*Defined as patients with del(17p), t(4;14), and/or t(14;16).

† 95% CI, 17.0-NE and 95% CI, 12.9-17.6, respectively; HR=0.74 (95% CI, 0.59-0.94); P=0.012.

‡ Defined as treatment to progression or unacceptable toxicity.


Please see accompanying Brief Summary.
5.1 Thrombocytopenia: Thrombocytopenia has been reported with NINLARO with platelet nadirs typically occurring between Days 14-21 of each 28-day cycle and recovery to baseline by the start of the next cycle. Three percent of patients in the NINLARO regimen and 1% of patients in the placebo regimen had a platelet count ≤ 10,000/mm³ during treatment. Less than 1% of patients in both regimens had a platelet count ≤ 5000/mm³ during treatment. Discontinuations due to thrombocytopenia were similar in both regimens (< 1% of patients in the NINLARO regimen and 2% of patients in the placebo regimen discontinued one or more of the three drugs). The rate of platelet transfusions was 6% in the NINLARO regimen and 5% in the placebo regimen. Monitor platelet counts at least monthly during treatment with NINLARO. Consider more frequent monitoring during the first three cycles. Manage thrombocytopenia with dose modifications and platelet transfusions as per standard medical guidelines.

5.2 Gastrointestinal Toxicities: Diarrhea, constipation, nausea, and vomiting, have been reported with NINLARO, occasionally requiring use of antidiarrheal and antiemetic medications, and supportive care. Diarrhea was reported in 42% of patients in the NINLARO regimen and 36% in the placebo regimen, constipation in 34% and 25%, respectively, nausea in 26% and 21%, respectively, and vomiting in 22% and 11%, respectively. Diarrhea resulted in discontinuation of one or more of the three drugs in 1% of patients in the NINLARO regimen and < 1% of patients in the placebo regimen. Adjust dosing for Grade 3 or 4 symptoms.

5.3 Peripheral Neuropathy: The majority of peripheral neuropathy adverse reactions were Grade 1 (18% in the NINLARO regimen and 14% in the placebo regimen) and Grade 2 (8% in the NINLARO regimen and 5% in the placebo regimen). Grade 3 adverse reactions of peripheral neuropathy were reported at 2% in both regimens; there were no Grade 4 or serious adverse reactions. The most common reported reaction was peripheral sensory neuropathy (19% and 14% in the NINLARO and placebo regimen, respectively). Peripheral motor neuropathy was not commonly reported in either regimen (< 1%). Peripheral neuropathy resulted in discontinuation of one or more of the three drugs in 1% of patients in both regimens. Patients should be monitored for symptoms of neuropathy. Patients experiencing new or worsening peripheral neuropathy may require dose modification.

5.4 Peripheral Edema: Peripheral edema was reported in 25% and 18% of patients in the NINLARO and placebo regimens, respectively. The majority of peripheral edema adverse reactions were Grade 1 (16% in the NINLARO regimen and 13% in the placebo regimen) and Grade 2 (7% in the NINLARO regimen and 4% in the placebo regimen). Grade 3 peripheral edema was reported in 2% and 1% of patients in the NINLARO and placebo regimens, respectively. There was no Grade 4 peripheral edema reported. There were no discontinuations reported due to peripheral edema. Evaluate for underlying causes and provide supportive care, as necessary. Adjust dosing of dexamethasone per its prescribing information or NINLARO for Grade 3 or 4 symptoms.

5.5 Cutaneous Reactions: Rash was reported in 19% of patients in the NINLARO regimen and 11% of patients in the placebo regimen. The majority of the rash adverse reactions were Grade 1 (10% in the NINLARO regimen and 7% in the placebo regimen) or Grade 2 (6% in the NINLARO regimen and 3% in the placebo regimen). Grade 3 rash was reported in 3% of patients in the NINLARO regimen and 1% of patients in the placebo regimen. There were no Grade 4 or serious adverse reactions of rash reported. The most common type of rash reported in both regimens included maculo-papular and maculopapular rash. Rash resulted in discontinuation of one or more of the three drugs in < 1% of patients in both regimens. Manage rash with supportive care or with dose modification if Grade 2 or higher.

5.6 Thrombotic Microangiopathy: Cases, sometimes fatal, of thrombotic microangiopathy including thrombotic thrombocytopenic purpura/hemolytic uremic syndrome (TTP/HUS), have been reported in patients who received NINLARO. Monitor for signs and symptoms of TTP/HUS. If the diagnosis is suspected, stop NINLARO and evaluate. If the diagnosis of TTP/HUS is excluded, consider restarting NINLARO. The safety of reinitiating NINLARO therapy in patients previously experiencing TTP/HUS is not known.

5.7 Hepatotoxicity: Drug-induced liver injury, hepatocellular injury, hepatic steatosis, hepatitis cholestatic and hepatotoxicity have each been reported in < 1% of patients treated with NINLARO. Events of liver impairment have been reported (6% in the NINLARO regimen and 5% in the placebo regimen). Monitor hepatic enzymes regularly and adjust dosing for Grade 3 or 4 symptoms.

5.8 Embryo-Fetal Toxicity: NINLARO can cause fetal harm when administered to a pregnant woman based on the mechanism of action and findings in animals. There are no adequate and well-controlled studies in pregnant women using NINLARO. ixazomib caused embryo-fetal toxicity in pregnant rats and rabbits at doses resulting in exposures that were slightly higher than those observed in patients receiving the recommended dose. Females of reproductive potential should be advised to avoid becoming pregnant while being treated with NINLARO. If NINLARO is used during pregnancy or if the patient becomes pregnant while taking NINLARO, the patient should be apprised of the potential hazard to the fetus. Advise females of reproductive potential that they must use effective contraception during treatment with NINLARO and for 90 days following the final dose. Women using hormonal contraceptives should also use a barrier method of contraception.

6 ADVERSE REACTIONS

The following adverse reactions are described in detail in other sections of the prescribing information:

- Thrombocytopenia [see Warnings and Precautions (5.1)]
- Gastrointestinal Toxicities [see Warnings and Precautions (5.2)]
- Peripheral Neuropathy [see Warnings and Precautions (5.3)]
- Peripheral Edema [see Warnings and Precautions (5.4)]
- Cutaneous Reactions [see Warnings and Precautions (5.5)]
- Thrombotic Microangiopathy [see Warnings and Precautions (5.6)]
- Hepatotoxicity [see Warnings and Precautions (5.7)]

6.1 CLINICAL TRIALS EXPERIENCE

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

The safety population from the randomized, double-blind, placebo-controlled clinical study included 720 patients with relapsed and/or refractory multiple myeloma, who received NINLARO in combination with lenalidomide and dexamethasone (NINLARO regimen; N=360) or placebo in combination with lenalidomide and dexamethasone (placebo regimen; N=360).

The most frequently reported adverse reactions (> 20%) in the NINLARO regimen and greater than the placebo regimen were diarrhea, constipation, thrombocytopenia, peripheral neuropathy, nausea, peripheral edema, vomiting, and back pain. Serious adverse reactions reported in ≥ 2% of patients included thrombocytopenia (2%) and diarrhea (2%). For each adverse reaction, one or more of the three drugs was discontinued in ≤ 1% of patients in the NINLARO regimen.

Table 4: Non-Hematologic Adverse Reactions Occurring in ≥ 5% of Patients with a ≥ 5% Difference Between the NINLARO Regimen and the Placebo Regimen (All Grades, Grade 3 and Grade 4)

<table>
<thead>
<tr>
<th>Reaction</th>
<th>NINLARO + Lenalidomide and Dexamethasone N=360</th>
<th>Placebo + Lenalidomide and Dexamethasone N=360</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>All</strong></td>
<td><strong>Grade 3</strong></td>
<td><strong>Grade 4</strong></td>
</tr>
<tr>
<td>Infections and infections</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Upper respiratory tract infection</td>
<td>69 (19)</td>
<td>52 (14)</td>
</tr>
<tr>
<td><strong>Nervous system disorders</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Peripheral neuropathy*</td>
<td>100 (28)</td>
<td>77 (21)</td>
</tr>
<tr>
<td><strong>Gastrointestinal disorders</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diarrhea</td>
<td>151 (42)</td>
<td>130 (38)</td>
</tr>
<tr>
<td>Constipation</td>
<td>122 (34)</td>
<td>90 (25)</td>
</tr>
<tr>
<td>Nausea</td>
<td>92 (26)</td>
<td>74 (21)</td>
</tr>
<tr>
<td>Vomiting</td>
<td>79 (22)</td>
<td>38 (11)</td>
</tr>
<tr>
<td><strong>Skin and subcutaneous tissue disorders</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rash</td>
<td>68 (19)</td>
<td>38 (11)</td>
</tr>
<tr>
<td><strong>Musculoskeletal and connective tissue disorders</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Back pain</td>
<td>74 (21)</td>
<td>57 (18)</td>
</tr>
<tr>
<td><strong>General disorders and administration site conditions</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Edema peripheral</td>
<td>91 (25)</td>
<td>66 (18)</td>
</tr>
</tbody>
</table>

*Note: Adverse reactions included as preferred terms are based on MedDRA version 16.0.

*Represents a pooling of preferred terms (Continued on next page)
Table 5: Thrombocytopenia and Neutropenia

<table>
<thead>
<tr>
<th></th>
<th>NINLARO + Lenalidomide and Dexamethasone N=360</th>
<th>Placebo + Lenalidomide and Dexamethasone N=360</th>
</tr>
</thead>
<tbody>
<tr>
<td>Any Grade</td>
<td>Grade 3-4</td>
<td>Grade 3-4</td>
</tr>
<tr>
<td>Thrombocytopenia</td>
<td>281 (76)</td>
<td>196 (54)</td>
</tr>
<tr>
<td>Neutropenia</td>
<td>240 (67)</td>
<td>239 (66)</td>
</tr>
</tbody>
</table>

Herpes Zoster

Herpes zoster was reported in 4% of patients in the NINLARO regimen and 2% of patients in the placebo regimen. Antiviral prophylaxis was allowed at the physician's discretion. Patients treated in the NINLARO regimen who received antiviral prophylaxis had a lower incidence (<1%) of herpes zoster infection compared to patients who did not receive prophylaxis (6%).

Eye Disorders

Eye disorders were reported with many different preferred terms but in aggregate, the frequency was 26% in patients in the NINLARO regimen and 16% of patients in the placebo regimen. The most common adverse reactions were blurred vision (6% in the NINLARO regimen and 3% in the placebo regimen), dry eyes (5% in the NINLARO regimen and 1% in the placebo regimen), and conjunctivitis (6% in the NINLARO regimen and 1% in the placebo regimen).

Grade 3 adverse reactions were reported in 2% of patients in the NINLARO regimen and 1% in the placebo regimen.

Adverse Reactions Reported Outside of the Randomized Controlled Trial

The following serious adverse reactions have each been reported at a frequency of <1%: acute febrile neutrophilic dermatosis (Sweet's syndrome), Stevens-Johnson syndrome, transverse myelitis, posterior reversible encephalopathy syndrome, tumor lysis syndrome, and thrombotic thrombocytopenic purpura.

7 DRUG INTERACTIONS

7.1 Strong CYP3A Inducers: Avoid concomitant administration of NINLARO with strong CYP3A inducers (such as rifampin, phenytoin, carbamazepine, and St. John's Wort).

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy: Risk Summary: Based on its mechanism of action and data from animal reproduction studies, NINLARO can cause fetal harm when administered to a pregnant woman. There are no human data available regarding the potential effect of NINLARO on pregnancy or development of the embryo or fetus. Loxazolam caused embryo-fetal toxicity in pregnant rats and rabbits at doses resulting in exposures that were slightly higher than those observed in patients receiving the recommended dose. Advise women of the potential risk to a fetus and to avoid becoming pregnant while being treated with NINLARO. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2-4% and 15-20%, respectively. Animal Data: In an embryo-fetal development study in pregnant rabbits there were increases in fetal skeletal variations/abnormalities (caudal vertebrae, number of lumbar vertebrae, and full supernumerary ribs) at doses that were also maternally toxic (≥0.3 mg/kg). Exposures in the rabbit at 0.3 mg/kg were 1.9 times the clinical time averaged exposures at the recommended dose of 4 mg. In a rat dose range-finding embryo-fetal development study, at doses that were maternally toxic, there were decreases in fetal weights, a trend towards decreased fetal viability, and increased post-implantation losses at 0.6 mg/kg. Exposures in rats at the dose of 0.6 mg/kg was 2.5 times the clinical time averaged exposures at the recommended dose of 4 mg.

8.2 Lactation: Risk Summary: No data are available regarding the presence of NINLARO or its metabolites in human milk, the effects of the drug on the breastfed infant, or the effects of the drug on milk production. Because the potential for serious adverse reactions from NINLARO in breastfed infants is unknown, advise nursing women not to breastfeed during treatment with NINLARO and for 90 days after the last dose.

8.3 Females and Males of Reproductive Potential: Contraception: Male and female patients of childbearing potential must use effective contraceptive methods during and for 90 days following treatment with NINLARO. In patients with severe renal impairment or ESRD requiring dialysis, contraceptive measures need to be considered. Advise women using hormonal contraceptives to also use a barrier method of contraception.

8.4 Pediatric Use: Safety and effectiveness have not been established in pediatric patients.

8.5 Geriatric Use: Of the total number of subjects in clinical studies of NINLARO, 55% were 65 and over, while 17% were 75 and over. No overall differences in safety or effectiveness were observed between these subjects and younger subjects, and other reported clinical experience has not identified differences in responses between the elderly and younger patients, but greater sensitivity of some older individuals cannot be ruled out.

8.6 Hepatic Impairment: In patients with moderate or severe hepatic impairment, the mean AUC increased by 20% when compared to patients with normal hepatic function. Reduce the starting dose of NINLARO in patients with moderate or severe hepatic impairment.

8.7 Renal Impairment: In patients with severe renal impairment or ESRD requiring dialysis, the mean AUC increased by 39% when compared to patients with normal renal function. Reduce the starting dose of NINLARO in patients with severe renal impairment or ESRD requiring dialysis. NINLARO is not dialyzable and therefore can be administered without regard to the timing of dialysis.

10 OVERDOSAGE: There is no known specific antidote for NINLARO overdose. In the event of an overdose, monitor the patient for adverse reactions and provide appropriate supportive care.

17 PATIENT COUNSELING INFORMATION

Advise the patient to read the FDA-approved patient labeling (Patient Information). Dosing Instructions

• Instruct patients to take NINLARO exactly as prescribed.
• Advise patients to take NINLARO once a week on the same day and at approximately the same time for the first three weeks of a four week cycle.
• Advise patients to take NINLARO at least one hour before or at least two hours after food.
• Advise patients that NINLARO and dexamethasone should not be taken at the same time, because dexamethasone should be taken with food and NINLARO should not be taken with food.
• Advise patients to swallow the capsule whole with water. The capsule should not be crushed, chewed, or opened.
• Advise patients that direct contact with the capsule contents should be avoided. In case of capsule breakage, avoid direct contact of capsule contents with the skin or eyes. If contact occurs with the skin, wash thoroughly with soap and water. If contact occurs with the eyes, flush thoroughly with water.
• If a patient misses a dose, advise them to take the missed dose as long as the next scheduled dose is ≥ 72 hours away. Advise patients not to take a missed dose if it is within 72 hours of their next scheduled dose.
• If a patient vomits after taking a dose, advise them not to repeat the dose but resume dosing at the time of the next scheduled dose.
• Advise patients to store capsules in original packaging, and not to remove the capsule from the packaging until just prior to taking NINLARO.

Thrombocytopenia: Advise patients that they may experience low platelet counts (thrombocytopenia). Signs of thrombocytopenia may include bleeding and easy bruising [see Warnings and Precautions (5.1)].

Peripheral Neuropathy: Advise patients to contact their physicians if they experience new or worsening symptoms of peripheral neuropathy such as tingling, numbness, pain, a burning feeling in the feet or hands, or weakness in the arms or legs [see Warnings and Precautions (5.3)].

Peripheral Edema: Advise patients to contact their physicians if they experience unusual swelling of their extremities or weight gain due to swelling [see Warnings and Precautions (5.4)].

Cutaneous Reactions: Advise patients to contact their physicians if they experience new or worsening rash [see Warnings and Precautions (5.5)].

Thrombotic Microangiopathy: Advise patients to seek immediate medical attention if any signs or symptoms of thrombotic microangiopathy occur [see Warnings and Precautions (5.6)].

Hepatotoxicity: Advise patients to contact their physicians if they experience jaundice or right upper quadrant abdominal pain [see Warnings and Precautions (5.7)].

Other Adverse Reactions: Advise patients to contact their physicians if they experience signs and symptoms of acute febrile neutrophilic dermatosis (Sweet's syndrome), Stevens-Johnson syndrome, transverse myelitis, posterior reversible encephalopathy syndrome, tumor lysis syndrome, and thrombotic thrombocytopenic purpura [see Adverse Reactions (6.1)].

Pregnancy: Advise women of the potential risk to a fetus and to avoid becoming pregnant while being treated with NINLARO and for 90 days following the final dose. Advise women using hormonal contraceptives to also use a barrier method of contraception. Advise patients to contact their physicians immediately if they or their female partner become pregnant during treatment or within 90 days of the final dose [see Warnings and Precautions (5.8)].

Concomitant Medications: Advise patients to speak with their physicians about any other medication they are currently taking and before starting any new medications.

Please see full Prescribing Information for NINLARO at NINLAROhcp.com.

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