Hematologic Malignancies™

Exhibit Guide

- **Congress Dates**
  October 14 - 15, 2022
  New York Marriott Marquis
  New York, NY

- **In-Person and Virtual Exhibits**
  October 14 - 15, 2022

- **Exhibit Hall Hours**
  Friday, October 14, 2022
  7:00 – 8:00 AM
  10:25 – 10:45 AM
  11:45 AM – 12:45 PM
  2:50 – 3:10 PM
  5:00 – 6:00 PM

  Saturday, October 15, 2022
  7:00 – 8:00 AM
  10:10 – 10:30 AM

NCCN.org/hem
NCCN 2022 Annual Congress: Hematologic Malignancies™

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Exhibitor Showcase Presentation
Non-CE Presentation

Friday, October 14
11:50 AM – 12:20 PM EDT
Pivotal Phase 3 Data In Newly Diagnosed AML
Presented by Genentech
24-hour inhibition of BTK was maintained at 100% in PBMCs and 94% to 100% in lymph nodes when taken at the recommended total daily dose of 320 mg. The clinical significance of 100% inhibition has not been established.12

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

Hemorrhage
Fatal and serious hemorrhagic events have occurred in patients with hematological malignancies treated with BRUKINSA monotherapy. Grade 3 or higher hemorrhage events including intracranial and gastrointestinal hemorrhage, hematuria and hemothorax have been reported in 3.4% of patients treated with BRUKINSA monotherapy. Hemorrhage events of any grade occurred in 35% of patients treated with BRUKINSA monotherapy. Bleeding events have occurred in patients with and without concomitant antiplatelet or anticoagulation therapy. Co-administration of BRUKINSA with antiplatelet or anticoagulant medications may further increase the risk of hemorrhage. Monitor for signs and symptoms of bleeding. Discontinue BRUKINSA if intracranial hemorrhage of any grade occurs. Consider the benefit-risk of withholding BRUKINSA for 3-7 days pre- and post-surgery depending upon the type of surgery and the risk of bleeding.

Infections
Fatal and serious infections (including bacterial, viral, or fungal) and opportunistic infections have occurred in patients with hematological malignancies treated with BRUKINSA monotherapy. Grade 3 or higher infections occurred in 27% of patients, most commonly pneumonia. Infections due to hepatitis B virus (HBV) reactivation have occurred. Consider prophylaxis for herpes simplex virus, pneumocystis jiroveci pneumonia and other infections according to standard of care in patients who are at increased risk for infections. Monitor and evaluate patients for fever or other signs and symptoms of infection and treat appropriately. Cytopenias Grade 3 or 4 cytopenias, including neutropenia (26%), thrombocytopenia (11%) and anemia (8%) based on laboratory measurements, were reported in patients treated with BRUKINSA monotherapy. Grade 4 neutropenia occurred in 13% of patients, and Grade 4 thrombocytopenia occurred in 3.6% of patients. Monitor complete blood counts regularly during treatment and interrupt treatment, reduce the dose or discontinue treatment as warranted. Treat using growth factor or transfusions, as needed.

Second Primary Malignancies
Second primary malignancies, including non-skin carcinoma, have occurred in 14% of patients treated with BRUKINSA monotherapy. The most frequent second primary malignancy was non-melanoma skin cancer reported in 8% of patients. Other second primary malignancies included malignant solid tumors (4.0%), melanoma (1.7%) and hematologic malignancies (1.2%). Advise patients to use sun protection, and monitor patients for the development of second primary malignancies. Cardiac Arrhythmias Atrial fibrillation and atrial flutter were reported in 3.2% of patients treated with BRUKINSA monotherapy. Patients with cardiac risk factors, hypertension and acute infections may be at increased risk. Grade 3 or higher events were reported in 1.1% of patients treated with BRUKINSA monotherapy. Monitor signs and symptoms for atrial fibrillation and atrial flutter and manage as appropriate.

Embryo-Fetal Toxicity
Based on findings in animals, BRUKINSA can cause embryo-fetal toxicity including malformations and manage as appropriate.

ADVERSE REACTIONS
The most common adverse reactions, including laboratory abnormalities, in ≥ 30% of patients who received BRUKINSA (N=847) included decreased neutrophil count (54%), upper respiratory tract infection (47%), decreased platelet count (41%), and hemorrhage (35%), decreased lymphocyte count (31%), rash (31%) and musculoskeletal pain (30%).

DRUG INTERACTIONS

CYP3A Inhibitors: When BRUKINSA is co-administered with a strong CYP3A inhibitor, reduce BRUKINSA dose to 80 mg once daily. For co-administration with a moderate CYP3A inhibitor, reduce BRUKINSA dose to 80 mg twice daily.

CYP3A Inducers: Avoid co-administration with moderate or strong CYP3A inducers.

SPECIFIC POPULATIONS

Hepatic Impairment: The recommended dose of BRUKINSA for patients with severe hepatic impairment is 80 mg orally twice daily.

See Brief Summary of full Prescribing Information on following pages.
THE BTK INHIBITOR THAT DELIVERS POWERFUL AND CONSISTENT RESPONSES

BRUKINSA® (zanubrutinib) is a kinase inhibitor indicated for the treatment of adult patients with Waldenström’s macroglobulinemia.

A global, randomized Phase 3 trial in WM across a range of patients*:
- Treatment-naïve
- Relapsed/refractory
- MYD88<sup>MUT</sup> (CXCR4<sup>WT</sup>, CXCR4<sup>MUT</sup>)
- MYD88<sup>WT</sup>

Powerful Responses Across WM Patients

While the primary endpoint of superiority did not reach statistical significance, numerically higher VGPR/CR rates were achieved in the BRUKINSA treatment arm.†

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<td>BRUKINSA (n=102)</td>
<td>78% VGPR+PR&lt;sup&gt;‡&lt;/sup&gt; (95% CI: 68, 85)</td>
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<td>Ibrutinib (n=99)</td>
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Median follow-up time was 19.4 months.³
The prespecified efficacy outcome measure of VGPR/CR was assessed by IRC.⁴

Safety in WM is consistent with the established BRUKINSA profile†

Serious adverse reactions, including fatal events, have occurred with BRUKINSA, including hemorrhage, infections, cytopenias, second primary malignancies, and cardiac arrhythmias. The most common adverse reactions (≥30%) include neutrophil count decreased, upper respiratory tract infection, platelet count decreased, hemorrhage, lymphocyte count decreased, rash, and musculoskeletal pain.


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LEARN MORE AT BRUKINSA.com
The median age of patients who received BRUKINSA in studies BGB-3111-206 and BGB-3111-AU-003 was 70 years (range: 45-87 years old); 67% were male, 86% were White, 4% were Asian and 10% were not reported (unknown race).

In Cohort 1, serious adverse reactions occurred in 44% of patients who received BRUKINSA. Serious adverse reactions leading to drug discontinuation occurred in 2 patients (4%), leading to treatment discontinuation occurred in 8 patients (17%).

Among patients who received BRUKINSA, 93% were exposed for 6 months or longer, and 89% were exposed for greater than one year.

In Cohort 1 of the APRN study safety population (N=101), the median age of patients who received BRUKINSA was 70 years (range: 45-87 years old); 67% were male, 86% were White, 4% were Asian and 10% were not reported (unknown race).

In Cohort 2 of the APRN study safety population (N=28), the median age of patients who received BRUKINSA was 72 years (range: 39-87 years old); 50% were male, 96% were White and 4% were not reported (unknown race).

In Cohort 1, serious adverse reactions occurred in 44% of patients who received BRUKINSA. Serious adverse reactions included pneumonia and cardiovascular adverse reactions such as myocardial infarction. In Cohort 2, serious adverse reactions occurred in 39% of patients. Serious adverse reactions included pneumonia and hemodynamic adverse reactions such as hypotension.

Permanent discontinuation of BRUKINSA due to an adverse reaction occurred in 2% of patients in Cohort 1 and included hemorrhage (1 patient), neutropenia and neutrophil count decreased (1 patient); in Cohort 2, permanent discontinuation of BRUKINSA due to an adverse reaction occurred in 7% of patients and included substantial hemorrhage (1 patient) and diarrhea (1 patient).

Dose interruptions of BRUKINSA due to an adverse reaction occurred in 32% of patients in Cohort 1 and 29% in Cohort 2. Dose reductions which required dosage interruption in ≥ 2% of patients included neutropenia, vomiting, hypertension, thrombocytopenia and pneumonia in Cohort 1. Adverse reactions leading to dosage interruption in ≥ 2 patients included pneumonia and hypotension.

Other clinically significant adverse reactions that occurred in ≥ 10% of patients with mantle cell lymphoma include major hemorrhage defined as grade 3 hemorrhage or CNE hemorrhage at any grade (5%), hypertension (9%) and headache (4%).

The safety of BRUKINSA was investigated in two cohorts of Study BGB-3111-302 (APRN). Cohort 1 included 199 patients withMYD88 mutation (MYD88*)/WM, randomized to treated with either BRUKINSA (198 patients) or Bruton’s (9 patients).

More patients in Cohort 2 had experienced previous hematological malignancies (14%) compared to Cohort 1 (8%). In Cohort 2, the median age of patients who received BRUKINSA was 67 years (range: 45-87 years old); 62% were male, 89% were White, 2% were Asian and 9% were not reported (unknown race).

Among patients who received BRUKINSA, 51% were exposed for 12 months or longer, and 47% were exposed for greater than one year.

In Cohort 2, one patient in the Bruton’s cohort died of unknown cause. In Cohort 1, one patient died of unknown cause in the BRUKINSA treated group. In Cohort 2, one patient died of unknown cause in the placebo-treated group.

In Cohort 1, 6 patients died of unknown cause, 4 patients died of unknown cause, 2 patients died of unknown cause and 1 patient died of unknown cause. In Cohort 2, 1 patient died of unknown cause, 1 patient died of unknown cause and 1 patient died of unknown cause.

In Cohort 1, 17 patients died of unknown cause, 13 patients died of unknown cause, 8 patients died of unknown cause and 4 patients died of unknown cause. In Cohort 2, 11 patients died of unknown cause, 9 patients died of unknown cause, 6 patients died of unknown cause and 5 patients died of unknown cause.

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The data in the WARNINGS AND PRECAUTIONS reflect exposure to BRUKINSA in seven clinical trials, administered as a single 160 mg dose twice daily (N = 204). BRUKINSA is indicated for the treatment of adult patients with relapsed or refractory marginal zone lymphoma (MZL) who have received at least one anti-CD20-based regimen.

Based on findings in animals, BRUKINSA can cause fetal harm when administered to a pregnant woman. Administration in pregnant rabbits during the period of organogenesis at doses of 30, 75, and 150 mg/kg/day resulted in malformations in the heart, including atrioventricular septal defects, pulmonic stenosis, and cleft palate. Administration of zanubrutinib to pregnant rabbits during the period of organogenesis at 30, 70, and 150 mg/kg/day resulted in an increased incidence of fetal resorptions. Administration of zanubrutinib to pregnant rats during the period of organogenesis at doses of 30, 75, and 150 mg/kg/day resulted in an increased incidence of postimplantation loss and an increased incidence of fetal resorptions. Administration of zanubrutinib to pregnant rats during the period of organogenesis at doses of 30, 75, and 150 mg/kg/day resulted in an increased incidence of postimplantation loss at the highest dose. The dose of 150 mg/kg is approximately 23 times the exposure (AUC) in patients at the recommended dose and was associated with maternal toxicity. The estimated background risk of major birth defects and miscarriage for the indicated population is unknown. All pregnancies have a background risk of birth defects, loss, or other adverse outcomes. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 26% to 4% and 15% to 20%, respectively.

Data

Clinical study data from early development toxicity studies were conducted in both rats and rabbits. Zanubrutinib was administered orally to pregnant rats during the period of organogenesis at doses of 30, 75, and 150 mg/kg/day. Malformations in the heart (3- or 5-mm hearts) were noted at all dose levels in the absence of maternal toxicity. The dose of 150 mg/kg is approximately 5 times the AUC in patients receiving the recommended dose.

8.2 Lactation

There are no data on the presence of zanubrutinib or its metabolites in human milk, the effects on the breastfed child, or the effects of milk production. Because of the potential for serious adverse reactions from BRUKINSA in a breastfed child, advise lactating women not to breastfeed during treatment with BRUKINSA and for 1 week following the last dose of BRUKINSA.

8.3 Females and Males of Reproductive Potential

Pregnancy Testing

Fertility

BRUKINSA can cause embryo-fetal harm when administered to pregnant women. (See Use in Specific Populations (8.1).) Advise males of reproductive potential to use effective contraception during treatment with BRUKINSA for 1 week following the last dose of BRUKINSA. If the drug is used during pregnancy, or if the patient becomes pregnant while receiving this drug, the patient should be informed of the potential hazard to the fetus. Males

Advise men to avoid fathering a child while receiving BRUKINSA and for 1 week following the last dose of BRUKINSA.

8.4 Pediatric Use

Safety and effectiveness in pediatric patients have not been established.

8.5 Carcinogenesis, Mutagenesis, Impairment of Fertility

The safety of BRUKINSA was evaluated in 60 patients with previously treated MZL in two single-arm clinical studies, BGB-3111-214 and BGB-3111-302 (NCT03741064). The trials required an absolute neutrophil count ≥ 1 x 10^9/L, platelet count ≥ 50 x 10^9/L, and adequate hepatic function and excluded patients requiring a strong CYP3A inhibitor or inducer. Patients received BRUKINSA 160 mg twice daily (N = 330 mg once daily (N = 167). The median age in both studies combined was 70 years (range: 37 to 95), 57% were male, 64% were Caucasian and 19% were Asian. Most patients (60%) had an ECOG performance status of 0 or 1. Eighty percent received BRUKINSA for 6 months or longer, and 67% received treatment for more than one year. Two fatal adverse reactions (2.3%) occurred within 30 days of the last dose of BRUKINSA, including myocardial infarction and a COVID-19 related death.

Serious adverse reactions occurred in 40% of patients. The most frequent serious adverse reactions were pyrexia (8%) and pneumonia (7%). Adverse reactions lead to treatment discontinuation in 6% of patients, dose reduction in 2.3%, and dose interruption in 34%.

The leading cause of dose modification was respiratory tract infections (3%). Table 7 shows the most common adverse reactions in patients treated with BRUKINSA. Table 7: Adverse Reactions Occurring in ≥ 10% of Patients with MZL Who Received BRUKINSA

Table 8: Select Laboratory Abnormalities

The most frequent adverse reactions leading to treatment discontinuation were pneumonia (3.4%), upper respiratory tract infection (3.4%), upper respiratory tract infection viral (3.4%), rash pruritic (2.3%), and nausea (2.3%). Upper respiratory tract infection includes upper respiratory tract infection, nasopharyngitis, sinusitis, bronchitis, rhinitis, viral upper respiratory tract infection, and sinusitis.

Table 8: Laboratory Abnormalities

The common adverse reactions leading to treatment discontinuation were cough (3.4%), pyrexia (3.4%), and pneumonia (3.4%). The most common adverse reactions leading to treatment discontinuation were upper respiratory tract infection (3.4%), pneumonitis (3.4%), and pneumonia (3.4%). The most common adverse reactions leading to treatment discontinuation were upper respiratory tract infection (3.4%), pneumonitis (3.4%), and pneumonia (3.4%).
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About Our Exhibitors

AbbVie Oncology  Table # 29
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 http://www.abbvie.com/oncology

ADC Therapeutics  Table # 22
Confronting cancer with the full potential of our science. ADC Therapeutics is a commercial-stage biotechnology company improving the lives of cancer patients with its next-generation, targeted antibody drug conjugates (ADCs). ADC Therapeutics is advancing its proprietary PBD-based ADC technology to transform the treatment paradigm for patients with hematologic malignancies and solid tumors.

AstraZeneca  Table # 18
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 therapeutic areas - Oncology, Cardiovascular, Renal & Metabolism and Respiratory & Immunology. For more information, please visit www.astrazeneca-us.com and follow us on Twitter @AstraZenecaUS

BeiGene  Table # 3
BeiGene is a global, commercial-stage biotechnology company focused on discovering, developing, manufacturing, and commercializing innovative medicines to improve treatment outcomes and access for patients worldwide. We currently market an internally discovered product in the United States, BRUKINSA® (zanubrutinib).

Blueprint Medicines  Table # 36
Blueprint Medicines is a global precision therapy company that aims to invent medicines for people with cancer and hematologic disorders.

Bristol Myers Squibb  Table # 31
Bristol Myers Squibb is a leading global biopharma company focused on discovering, developing and delivering innovative medicines for patients with serious diseases in areas including oncology, hematology, immunology, cardiovascular, fibrosis and neuroscience. Our employees work every day to transform patients’ lives through science.

Fresenius Kabi USA, LLC  Table # 17
Fresenius Kabi has been supplying oncology medicines in the United States for more than a quarter of a century, and today we are building on our expansive portfolio and deep experience by developing a range of biosimilar medicines for oncology as well as immunology. We have already launched biosimilars in Europe, Australia and Canada, turning the promise of effective and affordable biologic therapies into reality for many patients. And now we are poised to bring high-quality biosimilars to the United States. From the collaborative way we work with health care professionals and patients, to how we manufacture and deliver our products – you can be confident that we are experienced, innovative and dedicated to the future of biosimilars. We are BioSpecialized.

Genentech  Table # 23
For more than 40 years, we’ve been following the science, seeking solutions to unmet medical needs. As a proud member of the Roche Group, we make medicines to treat patients with serious medical conditions.

Gilead and Kite Oncology  Table # 2
Gilead and Kite Oncology are creating the future of oncology. From antibody-drug conjugates and small molecules to cell therapy-based approaches, our R&D programs and partnerships are creating possibilities for people with overlooked, underserved and difficult-to-treat cancers. We are focused on helping to bring more life to people with cancer and changing the way cancer is treated.

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All registered attendees can use the log-in information provided for access to the Congress.
About Our Exhibitors

Harborside Table # 8
Harborside is the publisher of *JNCCN-Journal of the National Comprehensive Cancer Network*, covering the entire spectrum of cancer care; *The ASCO Post*, a newspaper featuring coverage of important issues in the field of oncology; *JOP*, providing research to inform the delivery of efficient, quality cancer care; and *Journal of the JADPRO*, a clinical journal for the NP, CNS and PAs. Harborside provides advertising services for *Journal of Clinical Oncology*, *Journal of Global Oncology*, *JCO Clinical Informatics*, and *JCO Precision Oncology*.

Incyte Corporation Table # 19
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 Oncology and Inflammation & Autoimmunity. Headquartered in Wilmington, Delaware, Incyte has operations in North America, Europe and Asia. For more information, visit [Incyte.com](http://Incyte.com) and follow @Incyte.

Janssen Biotech Table # 7
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. Learn more at [www.janssen.com](http://www.janssen.com). Follow us at [www.twitter.com/JanssenUS](http://www.twitter.com/JanssenUS).

Jazz Pharmaceuticals Table # 34
Jazz Pharmaceuticals plc (Nasdaq: JAZZ) is a global biopharmaceutical company dedicated to developing medicines for people with serious diseases — often with limited or no options. We have a diverse portfolio of marketed medicines and novel product candidates, from early- to late-stage development, in key therapeutic areas. Our focus is neuroscience, including sleep medicine and movement disorders, and oncology, including hematologic and solid tumors. We actively explore new options for patients including novel compounds, small molecule advancements, biologics and innovative delivery technologies. Jazz is headquartered in Dublin, Ireland and has employees around the globe, serving patients in more than 90 countries.

Karyopharm Therapeutics, Inc. Table # 20
Karyopharm Therapeutics Inc. is a commercial-stage pharmaceutical company pioneering novel cancer therapies dedicated to the discovery, development, and commercialization of novel first-in-class drugs for the treatment of cancer and other diseases. Karyopharm’s Selective Inhibitor of Nuclear Export (SINE) compounds function by binding with and inhibiting the nuclear export protein XPO1. The company was founded in 2008 with a vision of pioneering a potentially new approach to treating patients with certain blood cancers.

Kite and Gilead Oncology Table # 33
Kite, a Gilead Company, is a global biopharmaceutical company based in Santa Monica, California, with manufacturing operations in North America and Europe. Kite’s singular focus is cell therapy to treat and potentially cure cancer. As the cell therapy leader, Kite has more approved CAR T indications to help more patients than any other company.

Pharmacyclics LLC., an AbbVie Company Table # 1
Pharmacyclics is an AbbVie company based in South San Francisco, California and focused on developing and commercializing small-molecule medicines for the treatment of cancers and immune-mediated diseases for which there is great unmet medical need. We seek to discover innovative therapies to improve standards of care and strive to help our patients rediscover the Magic of Normal.

PharmaEssentia USA Corporation Table # 30
PharmaEssentia Corporation (TPEx: 6446), based in Taipei, Taiwan, is a rapidly growing biopharmaceutical innovator. Leveraging deep expertise and proven scientific principles, the company aims to deliver effective new biologics for challenging diseases in the areas of hematology and oncology, with one approved product.

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About Our Exhibitors

and a diversifying pipeline. Founded in 2003 by a team of Taiwanese-American executives and renowned scientists from U.S. biotechnology and pharmaceutical companies, today the company is expanding its global presence with operations in the U.S., Japan, China, and Korea, along with a world-class biologics production facility in Taichung. For more information, visit our website or find us on LinkedIn and Twitter.

Rigel Pharmaceuticals

Rigel Pharmaceuticals is a biotechnology company dedicated to improving the lives of patients through the development and commercialization of novel small molecule drugs. Rigel is focused on immune and hematologic disorders, cancer, and rare diseases and see great opportunity to help patients who have diseases where few to no approved treatment options exist. Rigel's first FDA approved product TAVALISSE® (fostamatinib disodium hexahydrate) tablets was approved in 2018. Please visit www.TAVALISSEhcp.com to see the full Prescribing Information and learn more.

Sanofi

Sanofi is an innovative global healthcare company, driven by one purpose: we chase the miracles of science to improve people's lives. Our teams across the world strive to transform the practice of medicine for patients. Our approach is shaped by our experience developing specialized treatments and forging 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.

Seagen Inc.

Seagen Inc. is a global biotechnology company that discovers, develops, and commercializes medicines for cancer. The company has a pipeline of therapies at various stages of preclinical testing, clinical testing, and development. We are leveraging our expertise in antibodies to build a portfolio of proprietary antibody-drug conjugates and immuno-oncology agents in clinical trials for hematologic malignancies and solid tumors. For more information, visit www.seagen.com.

Servier Pharmaceuticals

Servier Pharmaceuticals is a commercial-stage pharmaceuticals company with a passion for innovation and improving the lives of patients, their families and caregivers. In the United States, Servier Pharmaceuticals is committed to building a robust portfolio, starting with oncology, with future growth driven by innovation in other areas of unmet medical need, leveraging Servier's global portfolio and seeking acquisitions, licensing deals and partnerships. With our commercial and scientific expertise, global reach and commitment to clinical excellence, Servier Pharmaceuticals is dedicated to bringing the promise of tomorrow to the patients that we serve.

Sobi

Sobi is an international biopharmaceutical company focused on rare diseases. We are dedicated to providing access to innovative treatments that transform life for people with rare diseases.

Taiho Oncology, Inc.

Taiho Oncology, Inc., a division of Taiho Pharmaceutical Co., Ltd. and Otsuka Holdings Co., Ltd., has built a world class clinical development organization that works urgently to develop innovative cancer treatments and is in the process of building commercial businesses in the USA and Europe. Taiho 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. For more information about Taiho Oncology, please visit: www.taihooncology.com

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AAMDS Virtual Only
The world's leading nonprofit health organization dedicated to supporting patients and families living with aplastic anemia, myelodysplastic syndrome (MDS), paroxysmal nocturnal hemoglobinuria (PNH), and related bone marrow failure diseases. The Foundation provides answers, support, and hope to thousands of patients and their families around the world.

Bone Marrow & Cancer Foundation Kiosk # A3
The Bone Marrow & Cancer Foundation, founded in 1992, is dedicated to improving the quality of life for cancer and transplant patients and their families by providing vital financial assistance, comprehensive resources, educational information, physician referrals, and emotional support programs. Guided by a medical advisory board of nationally-recognized cancer specialists and working with hospitals across the United States, the Bone Marrow & Cancer Foundation is the only organization of its kind that does not limit assistance to a specific disease, type of transplant or age range. For the past 30 years, the Foundation has connected patients and their families with the services they need—from diagnosis through survivorship—to make effective decisions about treatment and its aftermath. All of the Foundation's programs and services are offered to patients and their families free of charge.

CLL Society Virtual Only
CLL Society is an inclusive, patient-centric, physician-curated nonprofit organization that addresses the unmet needs of the chronic lymphocytic leukemia and small lymphocytic lymphoma (CLL/SLL) community through patient education, advocacy, support, and research. We explain the rapidly changing therapeutic landscape and the importance of clinical trials, build patient support networks, engage in research, and educate providers and patients. We believe SMART PATIENTS GET SMART CARE™. Learn more at cllsociety.org.

HealthTree Foundation Virtual Only
HealthTree is a patient-driven nonprofit that empowers patients at each step of their disease journey — from diagnosis through education, care, and on to a cure.

International Myeloma Foundation (IMF) Virtual Only
The IMF's mission is to improve the quality of life of myeloma patients while working toward prevention and a cure. Founded in 1990, the International Myeloma Foundation (IMF) is the first and largest myeloma-specific charity in the world. With more than 525,000 members in 140 countries, the IMF serves myeloma patients, family members, and the medical community. The IMF provides a wide range of programs in the areas of Research, Education, Support, and Advocacy.

The Lymphoma Research Foundation Virtual Only
The Lymphoma Research Foundation is the nation's largest non-profit organization devoted exclusively to funding lymphoma research and supporting the lymphoma community through evidence-based education, support services, and resources.

The Cancer Support Community (CSC) Kiosk # A1
The Cancer Support Community (CSC) is a global non-profit network of 175 locations that together deliver more than $50 million in free support services to patients and families. In addition, CSC administers a toll-free helpline, vibrant online patient community, and produces award-winning educational resources that reach more than one million people each year. CSC also conducts cutting-edge research on the emotional, psychological and financial journey of cancer patients. In addition, CSC advocates at all levels of government for policies to help individuals whose lives have been disrupted by cancer. For more information, visit www.CancerSupportCommunity.org.

The Leukemia & Lymphoma Society (LLS) Kiosk # A2
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

MDS Foundation Virtual Only
MDS Foundation supports and educates patients, their communities, and healthcare providers, and contributes to innovative research in the fields of MDS and its related continuum of diseases to better diagnose, control and ultimately cure these diseases. patients and their families as well as healthcare The MDS Foundation is a global non-profit advocacy organization that for over 25 years has supported patients and their families as well as healthcare providers in the fields of MDS and its related diseases.

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OUT LIVING IT

First Descents provides life-changing outdoor adventures for young adults (ages 18-45) impacted by cancer and other serious health conditions empowering patients to surf, kayak and climb beyond their diagnosis and connect with others doing the same.

Our programs are free of charge, adaptive, and no prior experience is necessary. We provide beautiful lodging, expert guides, gear and instruction, and health-supportive meals prepared by professional chefs. Learn more at www.firstdescents.org

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.

myeloma.org | 1-800-452-2873 | TheIMF@myeloma.org
Find us at facebook.com/myeloma | Instagram @imfmyeloma | Twitter @IMFMyeloma

100% OF PARTICIPANTS REPORTED INCREASED ABILITY TO COPE WITH CANCER AND ITS EFFECTS

81% REPORTED INCREASED SELF-EFFICACY

17% TO 7% PARTICIPANTS WHO REPORTED FEELING DEPRESSED BEFORE AND AFTER FIRST DESCENTS

*First Descents partnered with the University of Michigan to evaluate the psychosocial benefits of FD programming. Top findings indicated an increase in self esteem, body image and participants ability to cope with cancer and its ongoing effects.
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Important Safety Information

Indications and Usage

Jakafi is indicated for treatment of intermediate or high-risk myelofibrosis (MF), including primary MF, post-polycythemia vera MF and post-essential thrombocythemia MF in adults.

Important Safety Information

- Treatment with Jakafi® (ruxolitinib) can cause thrombocytopenia, anemia and neutropenia, which are each dose-related effects. Perform a pre-treatment complete blood count (CBC) and monitor CBCs every 2 to 4 weeks until doses are stabilized, and then as clinically indicated.
- Manage thrombocytopenia by reducing the dose or temporarily interrupting Jakafi. Platelet transfusions may be necessary.
- Patients developing anemia may require blood transfusions and/or dose modifications of Jakafi.
- Severe neutropenia (ANC <0.5 × 10^9/L) was generally reversible by withholding Jakafi until recovery.
- Serious bacterial, mycobacterial, fungal and viral infections have occurred. Delay starting Jakafi until active serious infections have resolved. Observe patients receiving Jakafi for signs and symptoms of infection and manage promptly. Use active surveillance and prophylactic antibiotics according to clinical guidelines.
- Tuberculosis (TB) infection has been reported. Observe patients taking Jakafi for signs and symptoms of active TB and manage promptly. Prior to initiating Jakafi, evaluate patients for TB risk factors and test those at higher risk for latent infection. Consult a physician with expertise in the treatment of TB before starting Jakafi in patients with evidence of active or latent TB. Continuation of Jakafi during treatment of active TB should be based on the overall risk-benefit determination.
- Progressive multifocal leukoencephalopathy (PML) has occurred with Jakafi treatment. If PML is suspected, stop Jakafi and evaluate.
- Advise patients about early signs and symptoms of herpes zoster and to seek early treatment.
- Increases in hepatitis B viral load with or without associated elevations in alanine aminotransferase and aspartate aminotransferase have been reported in patients with chronic hepatitis B virus (HBV) infections. Monitor and treat patients with chronic HBV infection according to clinical guidelines.
- When discontinuing Jakafi, myeloproliferative neoplasm-related symptoms may return within one week. After discontinuation, some patients with myelofibrosis have experienced fever, respiratory distress, hypotension, DIC, or multi-organ failure. If any of these occur after discontinuation or while tapering Jakafi, evaluate and treat any intercurrent illness and consider restarting or increasing the dose of Jakafi. Instruct patients not to interrupt or discontinue Jakafi without consulting their physician. When discontinuing or interrupting Jakafi for reasons other than thrombocytopenia or neutropenia, consider gradual tapering rather than abrupt discontinuation.
- Non-melanoma skin cancers (NMSC) including basal cell, squamous cell, and Merkel cell carcinoma have occurred. Perform periodic skin examinations following pages. To learn more about Jakafi, visit STARTWITHJAKAFI.COM.

Merkel cell carcinoma have occurred. Perform periodic skin examinations following pages. To learn more about Jakafi, visit STARTWITHJAKAFI.COM.
Important Safety Information

Thrombocythemia MF in adults.

Jakafi is indicated for treatment of intermediate or high-risk myelofibrosis.

Indications and Usage

- Serious bacterial, mycobacterial, fungal and viral infections have occurred.
- Tuberculosis (TB) infection has been reported. Observe patients taking Jakafi for signs and symptoms of infection and manage.
- Manage thrombocytopenia by reducing the dose or temporarily interrupting treatment.
- Patients developing anemia may require blood transfusions and/or dose modifications of Jakafi.
- Severe neutropenia (ANC <0.5 × 10⁹/L) was generally reversible by treatment with Jakafi® (ruxolitinib) can cause thrombocytopenia, anemia and neutropenia, which are each dose-related effects. Perform a pre-treatment prompt evaluation of progression-driven events or at the physician’s discretion; however, these patients continued to be grouped within their original randomized assignment for analysis purposes.

Another JAK-inhibitor has increased the risk of major adverse cardiovascular events (MACE), including cardiovascular death, myocardial infarction, and stroke (compared to those treated with tumor TNF blockers) in patients with rheumatoid arthritis, a condition for which Jakafi is not indicated. Consider the benefits and risks for the individual patient prior to initiating or continuing therapy with Jakafi particularly in patients who are current or past smokers and patients with other cardiovascular risk factors. Patients should be informed about the symptoms of serious cardiovascular events and the steps to take if they occur.

Another JAK-inhibitor has increased the risk of thrombosis, including deep venous thrombosis (DVT), pulmonary embolism (PE), and arterial thrombosis (compared to those treated with TNF blockers) in patients with rheumatoid arthritis, a condition for which Jakafi is not indicated. In patients with myelofibrosis (MF) and polycythemia vera (PV) treated with Jakafi in clinical trials, the rates of thromboembolic events were similar in Jakafi and control treated patients. Patients with symptoms of thrombosis should be promptly evaluated and treated appropriately.

Another JAK-inhibitor has increased the risk of lymphoma and other malignancies excluding NMSC (compared to those treated with TNF blockers) in patients with rheumatoid arthritis, a condition for which Jakafi is not indicated. Patients who are current or past smokers are at increased risk. Consider the benefits and risks for the individual patient prior to initiating or continuing therapy with Jakafi, particularly in patients with a known secondary malignancy (other than a successfully treated NMSC), patients who develop a malignancy, and patients who are current or past smokers.

In myelofibrosis and polycythemia vera, the most common nonhematologic adverse reactions (incidence ≥15%) were bruising, dizziness, headache, and diarrhea. In acute graft-versus-host disease, the most common nonhematologic adverse reactions (incidence ≥5%) were infections (pathogen not specified) and edema. In chronic graft-versus-host disease, the most common nonhematologic adverse reactions (incidence ≥20%) were infections (pathogen not specified) and viral infections.

Avoid concomitant use with fluconazole doses greater than 200 mg. Dose modifications may be required when administering Jakafi with fluconazole doses of 200 mg or less, or with strong CYP3A4 inhibitors, or in patients with renal or hepatic impairment. Patients should be closely monitored and the dose titrated based on safety and efficacy.

Use of Jakafi during pregnancy is not recommended and should only be used if the potential benefit justifies the potential risk to the fetus. Women taking Jakafi should not breastfeed during treatment and for 2 weeks after the final dose.

References:


Jakafi and the Jakafi logo are registered trademarks of Incyte.
BRIEF SUMMARY: For Full Prescribing Information, see package insert.

INDICATIONS AND USAGE Myelofibrosis Jakafi is indicated for treatment of intermediate or high-risk myelofibrosis (MF), including primary MF, post-polycythemic, and post-essential thrombocythemia MF in adults. Polycythemia Vera Jakafi is indicated for treatment of polycythemia vera (PV) in adults who have had an inadequate response to or are intolerant of hydroxyurea. Acute Graft-Versus-Host Disease Jakafi is indicated for treatment of steroid-refractory acute graft-versus-host disease (aGVHD) in adult and pediatric patients 12 years and older. Chronic Graft-Versus-Host Disease Jakafi is indicated for treatment of chronic graft-versus-host disease (cGVHD) after failure of one or two lines of systemic therapy in adult and pediatric patients 12 years and older.

CONTRAINDICATIONS:

WARNINGS AND PRECAUTIONS

Thrombocytopenia, Anemia and Neutropenia Treatment with Jakafi can cause thrombocytopenia, anemia, and neutropenia. [see Adverse Reactions (6.1) in Full Prescribing Information]. Manage thrombocytopenia reducing the dose temporarily interrupting Jakafi. Platelet transfusions may be necessary [see Dosage and Administration (2) in Full Prescribing Information]. Patients developing anemia may require blood transfusions and/or dose modifications of Jakafi. Severe neutropenia (ANC less than 0.5 × 10^9/L) was generally reversible by withholding Jakafi until recovery. Perform a pre-treatment complete blood count (CBC) and monitor CBCs every 2 to 4 weeks until doses are stabilized, and then as clinically indicated [see Dosage and Administration in Full Prescribing Information].

Risk of Infection Serious bacterial, mycobacterial, fungal and viral infections have occurred [see Adverse Reactions (6.1) in Full Prescribing Information]. Delay starting therapy with Jakafi until active serious infections have resolved. Observe patients receiving Jakafi for signs and symptoms of infection and manage promptly. Use active surveillance and prophylactic antibiotics according to clinical guidelines. 

Tuberculosis Tuberculosis infection has been reported in patients receiving Jakafi. Observe patients receiving Jakafi for signs of active tuberculosis and manage promptly. Prior to initiating Jakafi, patients should be evaluated for tuberculosis risk factors, and those at higher risk should be tested for latent infection. Risk factors include, but are not limited to, prior residence in or travel to countries with a high prevalence of tuberculosis. 

Tuberculosis infection has been reported in patients treated with Jakafi. Consider the benefits and risks for the individual patient prior to initiating or continuing therapy with Jakafi particularly in patients who are current or past smokers and patients with other cardiovascular risk factors. Patients should be informed about the symptoms of serious cardiovascular events and the steps to take if they occur. 

Thrombosis Another Jak-kinase inhibitor has increased the risk of thrombosis, including deep venous thrombosis (DVT), pulmonary embolism and arterial thrombosis (compared to those treated with TNF blockers) in patients with rheumatoid arthritis, a condition for which Jakafi is not indicated. Consider the benefits and risks for the individual patient prior to initiating or continuing therapy with Jakafi in patients who received Jakafi in the double-blind, placebo-controlled study during randomized treatment.

Thrombocytopenia, anemia and neutropenia are dose-related effects. The three most frequent nonhematologic adverse reactions were bruising, dizziness and headache [see Table 1]. Discontinuation for adverse events, regardless of causality, was observed in 11% of patients treated with Jakafi while patients treated with control had 1% of patients treated with Jakafi. The most common nonhematologic adverse reactions occurring in patients who received Jakafi in the double-blind, placebo-controlled study during randomized treatment have been categorized as serious or not serious.

Table 1: Myelofibrosis: Nonhematologic Adverse Reactions Occurring in Patients on Jakafi in the Double-blind, Placebo-controlled Study During Randomized Treatment

<table>
<thead>
<tr>
<th>Adverse Reaction</th>
<th>Grade 3 (%)</th>
<th>Grade 4 (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bruising</td>
<td>23</td>
<td>1</td>
</tr>
<tr>
<td>Dizziness</td>
<td>18</td>
<td>1</td>
</tr>
<tr>
<td>Headache</td>
<td>15</td>
<td>0</td>
</tr>
<tr>
<td>Urinary Tract Infections</td>
<td>9</td>
<td>0</td>
</tr>
<tr>
<td>Weight Gain</td>
<td>7</td>
<td>1</td>
</tr>
<tr>
<td>Fatigue</td>
<td>5</td>
<td>0</td>
</tr>
<tr>
<td>Herpes Zoster</td>
<td>2</td>
<td>0</td>
</tr>
</tbody>
</table>

* Current National Cancer Institute Common Terminology Criteria for Adverse Events (CTCAE), version 3.0

Description of Selected Adverse Reactions: Anemia In the two Phase 3 clinical studies, median time to onset of first CTCAE Grade 2 or higher anemia was approximately 6 weeks. One patient (< 1%) discontinued treatment because of anemia. In patients receiving Jakafi, mean decreases in hemoglobin reached the nadir of approximately 1.5 to 2.0 g/dL below baseline after 8 to 12 weeks of therapy and then gradually recovered to reach a new steady state that was approximately 1.0 g/dL below baseline. This pattern was observed in patients regardless of whether they had received transfusions during therapy. In the randomized, placebo-controlled study, 60% of patients treated with Jakafi and 38% of patients receiving placebo received red blood cell transfusions during randomized treatment. Among transfused patients, the mean percent of patients who received one or more red blood cell transfusions during the first 12 weeks in patients treated with Jakafi and 1.7 in placebo treated patients.

Thrombocytopenia In the two Phase 3 clinical studies, in patients who developed Grade 3 or 4 thrombocytopenia, the median time to onset was approximately 6 weeks. Thrombocytopenia was generally reversible with dose reduction.

The median time to recovery of platelet counts above 50 × 10^9/L was 14 days. Platelet transfusions were administered to 3% of patients receiving Jakafi and to 4% of patients receiving control regimens. Discontinuation of treatment because of thrombocytopenia occurred in patients who have received Jakafi in the double-blind, placebo-controlled study during randomized treatment.
Table 2: Myelofibrosis: Worst Hematology Laboratory Abnormalities in the Placebo-Controlled Study*  

<table>
<thead>
<tr>
<th>Laboratory Parameter</th>
<th>Jakafi (N=159)</th>
<th>Placebo (N=151)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>All Grades^</td>
<td>Grade 3 (%)</td>
</tr>
<tr>
<td>Thrombocytopenia</td>
<td>70 9 4 31</td>
<td>1 0</td>
</tr>
<tr>
<td>Anemia</td>
<td>96 34 11 87</td>
<td>16 3</td>
</tr>
<tr>
<td>Neutropenia</td>
<td>19 5 2 4</td>
<td>&lt; 1 1</td>
</tr>
</tbody>
</table>

*Presented values are worst Grade values regardless of baseline  
^National Cancer Institute Common Terminology Criteria for Adverse Events, version 3.0  

Additional Data from the Placebo-Controlled Study  
- 25% of patients treated with Jakafi and 7% of patients treated with placebo developed newly occurring or worsening Grade 1 abnormalities in alanine transaminase (ALT). The incidence of greater than or equal to Grade 2 elevations was 2% for Jakafi with 1% Grade 3 and no Grade 4 ALT elevations.  
- 17% of patients treated with Jakafi and 6% of patients treated with placebo developed newly occurring or worsening Grade 1 abnormalities in aspartate transaminase (AST). The incidence of Grade 2 AST elevations was < 1% for Jakafi with no Grade 3 or 4 AST elevations.  
- 17% of patients treated with Jakafi and < 1% of patients treated with placebo developed newly occurring or worsening Grade 1 elevations in cholesterol.  
- The incidence of Grade 2 cholesterol elevations was < 1% for Jakafi with no Grade 3 or 4 cholesterol elevations. Polycythemia Vera in a randomized, open-label, active-controlled study, 110 patients with PV resistant to or intolerant of hydroxyurea received Jakafi and 111 patients received best available therapy [see Clinical Studies (14.2) in Full Prescribing Information]. The most frequent adverse reaction was anemia. Discontinuation for adverse events, regardless of causality, was observed in 4% of patients treated with Jakafi. Table 3 presents the most frequent nonhematologic adverse reactions occurring up to Week 32.  

Table 3: Polycythemia Vera: Nonhematologic Adverse Reactions Occurring in ≥ 5% of Patients on Jakafi in the Open-Label, Active-controlled Study up to Week 32 of Randomized Treatment  

<table>
<thead>
<tr>
<th>Adverse Reaction</th>
<th>Jakafi (N=110)</th>
<th>All Grades^</th>
<th>Grade 3-4 (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diarrhea</td>
<td>15 0 3 7 1 0</td>
<td>&lt; 1 2 0</td>
<td></td>
</tr>
<tr>
<td>Dyspeas^</td>
<td>15 0 3 7 1 0</td>
<td>&lt; 1 2 0</td>
<td></td>
</tr>
<tr>
<td>Muscle Spasms</td>
<td>12 1 5 0 0 0</td>
<td>&lt; 1 2 0</td>
<td></td>
</tr>
<tr>
<td>Constipation</td>
<td>6 1 1 0 0 0</td>
<td>&lt; 1 2 0</td>
<td></td>
</tr>
<tr>
<td>Herpes Zoster^</td>
<td>6 1 1 0 0 0</td>
<td>&lt; 1 2 0</td>
<td></td>
</tr>
<tr>
<td>Nausea</td>
<td>6 0 4 0 0 0</td>
<td>&lt; 1 2 0</td>
<td></td>
</tr>
</tbody>
</table>

^National Cancer Institute Common Terminology Criteria for Adverse Events (CTCAE), version 3.0  
^Includes diarrhea and vertigo  
^Includes dyspepsia and dyspepsia-exertional  
^Includes herpes zoster and post-herpetic neuritis  
^Includes weight increased and abnormal weight gain  
^Includes urinary tract infection and cystitis  

Table 4: Polycythemia Vera: Selected Laboratory Abnormalities in the Open-Label, Active-controlled Study up to Week 32 of Randomized Treatment  

<table>
<thead>
<tr>
<th>Laboratory Parameter</th>
<th>All Grades^</th>
<th>Grade 3 (%)</th>
<th>Grade 4 (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hematoma</td>
<td>Anemia</td>
<td>75 45</td>
<td>75 45</td>
</tr>
<tr>
<td></td>
<td>Thrombocytopenia</td>
<td>75 61</td>
<td>75 61</td>
</tr>
<tr>
<td></td>
<td>Neutropenia</td>
<td>58 40</td>
<td>58 40</td>
</tr>
</tbody>
</table>

^National Cancer Institute Common Terminology Criteria for Adverse Events, version 3.0  

Table 5: Acute Graft-Versus-Host Disease: Nonhematologic Adverse Reactions Occurring in ≥ 15% of Patients in the Open-Label, Single Cohort Study  

<table>
<thead>
<tr>
<th>Laboratory Parameter</th>
<th>All Grades^</th>
<th>Grade 3 (%)</th>
<th>Grade 4 (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hematology</td>
<td>Anemia</td>
<td>75 45</td>
<td>75 45</td>
</tr>
<tr>
<td></td>
<td>Thrombocytopenia</td>
<td>75 61</td>
<td>75 61</td>
</tr>
<tr>
<td></td>
<td>Neutropenia</td>
<td>58 40</td>
<td>58 40</td>
</tr>
</tbody>
</table>

^National Cancer Institute Common Terminology Criteria for Adverse Events, version 3.0  

Table 6: Acute Graft-Versus-Host Disease: Selected Laboratory Abnormalities Worsembling from Baseline in the Open-Label, Single Cohort Study  

<table>
<thead>
<tr>
<th>Laboratory Parameter</th>
<th>All Grades^</th>
<th>Grade 3 (%)</th>
<th>Grade 4 (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hematology</td>
<td>Anemia</td>
<td>75 45</td>
<td>75 45</td>
</tr>
<tr>
<td></td>
<td>Thrombocytopenia</td>
<td>75 61</td>
<td>75 61</td>
</tr>
<tr>
<td></td>
<td>Neutropenia</td>
<td>58 40</td>
<td>58 40</td>
</tr>
</tbody>
</table>

^National Cancer Institute Common Terminology Criteria for Adverse Events, version 3.0  

Table 7: Chronic Graft-Versus-Host Disease: All-Grade (> 10%) and Grades 3-5 (> 5%) Nonlaboratory Adverse Reactions Occurring in Patients in the Open-Label, Active-controlled Study up to Cycle 7 Day 1 of Randomized Treatment  

<table>
<thead>
<tr>
<th>Adverse Reactions^</th>
<th>Jakafi (N = 165)</th>
<th>All Grades^</th>
<th>Grade 3 (%)</th>
<th>Grade 4 (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Infections and infestations</td>
<td>45 15 44 16</td>
<td>45 15 44 16</td>
<td>45 15 44 16</td>
<td></td>
</tr>
<tr>
<td>Viral infections</td>
<td>28 5 23 5</td>
<td>28 5 23 5</td>
<td>28 5 23 5</td>
<td></td>
</tr>
<tr>
<td>Musculoskeletal and connective tissue disorders</td>
<td>16 1 13 0</td>
<td>16 1 13 0</td>
<td>16 1 13 0</td>
<td></td>
</tr>
<tr>
<td>Gastrointestinal disorders</td>
<td>12 0 13 2</td>
<td>12 0 13 2</td>
<td>12 0 13 2</td>
<td></td>
</tr>
</tbody>
</table>

^Grouped terms that are composites of applicable adverse reaction terms  

Table 8: Chronic Graft-Versus-Host Disease: Selected Laboratory Abnormalities in the Open-Label, Active-controlled Study up to Cycle 7 Day 1 of Randomized Treatment  

<table>
<thead>
<tr>
<th>Laboratory Parameter</th>
<th>All Grades^</th>
<th>Grade 3 (%)</th>
<th>Grade 4 (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hematology</td>
<td>Anemia</td>
<td>75 45</td>
<td>75 45</td>
</tr>
<tr>
<td></td>
<td>Thrombocytopenia</td>
<td>75 61</td>
<td>75 61</td>
</tr>
<tr>
<td></td>
<td>Neutropenia</td>
<td>58 40</td>
<td>58 40</td>
</tr>
</tbody>
</table>

^National Cancer Institute Common Terminology Criteria for Adverse Events (CTCAE), version 4.03  

Table 9: Chronic Graft-Versus-Host Disease: Adverse Reactions Occurring in Patients in the Open-Label, Active-controlled Study up to Cycle 7 Day 1 of Randomized Treatment  

<table>
<thead>
<tr>
<th>Adverse Reactions</th>
<th>Jakafi (N = 165)</th>
<th>All Grades^</th>
<th>Grade 3 (%)</th>
<th>Grade 4 (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Infections and infestations</td>
<td>45 15 44 16</td>
<td>45 15 44 16</td>
<td>45 15 44 16</td>
<td></td>
</tr>
<tr>
<td>Viral infections</td>
<td>28 5 23 5</td>
<td>28 5 23 5</td>
<td>28 5 23 5</td>
<td></td>
</tr>
<tr>
<td>Musculoskeletal and connective tissue disorders</td>
<td>16 1 13 0</td>
<td>16 1 13 0</td>
<td>16 1 13 0</td>
<td></td>
</tr>
<tr>
<td>Gastrointestinal disorders</td>
<td>12 0 13 2</td>
<td>12 0 13 2</td>
<td>12 0 13 2</td>
<td></td>
</tr>
</tbody>
</table>

^Grouped terms that are composites of applicable adverse reaction terms  

Clinically relevant laboratory abnormalities are shown in Table 4.
**Drug Interactions** Fluconazole Concomitant use of Jakafi with fluconazole increases ruxolitinib exposure [see Clinical Pharmacology (12.3)] in Full Prescribing Information], which may increase the risk of exposure-related adverse reactions. Avoid concomitant use of Jakafi with flucloxacillin doses of greater than 200 mg daily. Reduce the Jakafi dosage when used concomitantly with flucloxacillin doses of greater than or equal to 200 mg [see Dosage and Administration (2.5) in Full Prescribing Information].

**Strong CYP3A4 Inducers** Concomitant use of Jakafi with strong CYP3A4 inducers increases ruxolitinib exposure [see Clinical Pharmacology (12.3)] in Full Prescribing Information], which may increase the risk of exposure-related adverse reactions. Reduce the Jakafi dosage when used concomitantly with strong CYP3A4 inhibitors except in patients with aGVHD or cGVHD [see Dosage and Administration (2.5) in Full Prescribing Information].

**Strong CYP3A4 Inducers** Concomitant use of Jakafi with strong CYP3A4 inducers may decrease ruxolitinib exposure [see Clinical Pharmacology (12.3)] in Full Prescribing Information], which may reduce efficacy of Jakafi. Monitor patients frequently and adjust the Jakafi dose based on safety and efficacy [see Clinical Pharmacology (12.3) in Full Prescribing Information].

**Use in Specific Populations** Pregnancy: Risk Summary When pregnant rats and rabbits were administered ruxolitinib during the period of organogenesis adverse developmental outcomes occurred at doses with maternal toxicity [see Data]. There are no studies with the use of Jakafi in pregnant women to inform drug-associated risks. The background risk of major birth defects and miscarriage for the indicated populations is unknown. Adverse outcomes in pregnancy occur regardless of the health of the mother or the use of medications. The background risk in the U.S. general population of major birth defects is 2% to 4% and miscarriage is 15% to 20% of clinically recognized pregnancies. Data: Animal Data Ruxolitinib was administered orally to pregnant rats or rabbits during the period of organogenesis at doses of 15, 30 or 60 mg/kg/day in rats and 10, 30 or 60 mg/kg/day in rabbits. There were no treatment-related malformations. Adverse developmental outcomes, such as decreases of approximately 9% in fetal weights were noted in rats at the highest and maternally toxic dose of 60 mg/kg/day. This dose results in an exposure (AUC) that is approximately 2 times the clinical exposure at the maximum recommended dose of 25 mg twice daily. In rabbits, lower fetal weights of approximately 8% and increased late resorptions were noted at the highest and maternally toxic dose of 60 mg/kg/day. This dose is approximately 7% the clinical exposure at the maximum recommended dose. In a pre- and post-natal development study in rats, pregnant animals were dosed with ruxolitinib from implantation through lactation at doses up to 30 mg/kg/day. There were no drug-related adverse findings in pups for fertility indices or for maternally or embryofetal survival, growth and development parameters at the highest dose evaluated (34% the clinical exposure at the maximum recommended dose of 25 mg twice daily). Lactation: Risk Summary No data are available regarding the presence of ruxolitinib in human milk, the effects on the breast fed child, or the effects on milk production. Ruxolitinib and its metabolites were present in the milk of lactating rats (see Data). Because many drugs are present in human milk and because of the potential for thrombocytopenia and anemia shown for Jakafi in human studies, discontinue breastfeeding during treatment with Jakafi and for two weeks after the final dose. Data: Animal Data Administered a single dose of [14C]-labeled ruxolitinib (30 mg/kg) on postnatal Day 10, after which plasma and milk samples were collected for up to 24 hours. The AUC for total ruxolitinib and all at levels higher than those in maternal plasma. The presence of ruxolitinib and several of its metabolites in milk, all at levels higher than those in maternal plasma.

**Pediatric Use** The safety and effectiveness of Jakafi for treatment of myeloﬁbrosis or polycythemia vera in pediatric patients have not been established. The safety and effectiveness of Jakafi for treatment of steroid-refractory aGVHD has been established for treatment of children 12 years and older. Use of Jakafi in pediatric patients with steroid-refractory aGVHD [see Clinical Studies (14.3)] in Full Prescribing Information] and additional pharmacokinetic and safety data in pediatric patients. The safety and effectiveness of treatment of steroid-refractory aGVHD has not been established in pediatric patients younger than 12 years old. The safety and effectiveness of Jakafi for treatment of cGVHD after failure of one or two lines of systemic therapy has been established for treatment of children 12 years and older. Use of Jakafi in pediatric patients with cGVHD after failure of one or two lines of systemic therapy is supported by evidence from adequate and well-controlled trials of Jakafi in adults [see Clinical Studies (14.3, 14.4) in Full Prescribing Information] and additional pharmacokinetic and safety data in pediatric patients. The safety and effectiveness of Jakafi for treatment of cGVHD has not been established in pediatric patients younger than 12 years old. Jakafi was evaluated in a single-arm, dose-escalation study (NCT01164163) in 27 pediatric patients with relapsed or refractory solid tumors (Cohort A) and 20 with leukemias or myeloproliferative neoplasms (Cohort B). The patients had a median age of 14 years (range, 2 to 21 years) and included 18 children (age 2 to < 12 years), and 14 adolescents (age 12 to < 17 years). The dose levels tested were 15, 21, 29, 39, or 50 mg/m² twice daily in 28-day cycles with up to 6 patients per dose group. Overall, 38 (81%) patients were treated with no more than a single cycle of Jakafi, while 3, 1, 2, and 3 patients received 2, 3, 4, and 5 or more cycles, respectively. A protocol-defined maximal tolerated dose was not observed, but since few patients were treated for multiple cycles, tolerability with continued use was not assessed adequately to establish a recommended Phase 2 dose higher than the recommended dose for adults. The safety profile in children was similar to that seen in adults. Juvenile Animal Toxicity Data Administration of ruxolitinib to juvenile rats resulted in effects on growth and bone measures. When administered starting at postnatal day 7 (the equivalent of a human newborn) at doses of 1.5 to 75 mg/kg/day, evidence of fractures occurred at doses ≥ 30 mg/kg/day, and effects on body weight and other bone measures [e.g., bone mineral content, peripheral quantitative computed tomography, and x-ray analysis] occurred at doses ≥ 5 mg/kg/day. When administered starting at postnatal day 21 (the equivalent of a human 2-3 years of age) at doses of 5 to 60 mg/kg/day, effects on body weight and bone occurred at doses ≥ 15 mg/kg/day, which were considered adverse at 60 mg/kg/day. Males were more severely affected than females in all age groups, and effects were generally more severe when administration was initiated earlier in the postnatal period. These findings were observed at exposures that are at least 27% the clinical exposure at the maximum recommended dose of 25 mg twice daily. Geriatric Use Of the total number of patients with MF in clinical studies with Jakafi, 52% were 65 years or older, and 15% were 75 years and older. No overall differences in safety or effectiveness of Jakafi were observed between these patients and younger patients. Clinical studies of Jakafi in patients with aGVHD did not include sufficient numbers of subjects age 65 and over to determine whether they respond differently from younger subjects. Of the total number of patients with cGVHD treated with Jakafi in clinical trials, 11% were 65 years and older. No overall differences in safety or effectiveness of Jakafi were observed between these patients and younger patients. Renal Impairment Total exposure of ruxolitinib and its active metabolites increased with moderate (Clcr 30 to 59 mL/min) and severe (Clcr 15 to 29 mL/min) renal impairment, and ESRD (Clcr less than 15 mL/min) on dialysis [see Clinical Pharmacology (12.3)] in Full Prescribing Information]. Modify Jakafi dosage as recommended [see Dosage and Administration (2.6) in Full Prescribing Information].

**Hepatic Impairment** Exposure of ruxolitinib increased with mild (Child-Pugh A), moderate (Child-Pugh B) and severe (Child-Pugh C) hepatic impairment [see Clinical Pharmacology (12.3) in Full Prescribing Information].
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CALQUENCE is a Bruton tyrosine kinase (BTK) inhibitor indicated for the treatment of adult patients with mantle cell lymphoma (MCL) who have received at least one prior therapy. This indication is approved under accelerated approval based on overall response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

CALQUENCE is also indicated for the treatment of adult patients with chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL).

Select Safety Information

Serious adverse events, including fatal events, have occurred in patients with hematological malignancies treated with CALQUENCE, including serious and opportunistic infections, hemorrhage, cytopenias, second primary malignancies, and atrial fibrillation and flutter. The most common adverse reactions (≥20%) in patients with relapsed or refractory MCL were anemia, thrombocytopenia, headache, neutropenia, diarrhea, fatigue, myalgia, and bruising. The most common adverse reactions (≥30%) in patients with CLL were anemia, neutropenia, thrombocytopenia, headache, upper respiratory tract infection, and diarrhea.

Please see Brief Summary of Prescribing Information on adjacent pages.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.FDA.gov/medwatch or call 1-800-FDA-1088.

References:
2. CALQUENCE® (acalabrutinib) tablets [prescribing information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; 2022.

H2RAs=H2-receptor antagonists; PPIs=proton pump inhibitors.
CALQUENCE TABLETS:
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Select Safety Information
Serious adverse events, including fatal events, have occurred in patients with hematological malignancies treated with CALQUENCE, including serious and opportunistic infections, hemorrhage, cytopenias, second primary malignancies, and atrial fibrillation and flutter. The most common adverse reactions (≥20%) of any grade in patients with relapsed or refractory MCL were anemia, thrombocytopenia, headache, neutropenia, diarrhea, fatigue, myalgia, and bruising. The most common adverse reactions (≥30%) of any grade in patients with CLL were anemia, neutropenia, thrombocytopenia, headache, upper respiratory tract infection, and diarrhea.

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H2RAs=H2-receptor antagonists; PPIs=proton pump inhibitors.

*Same efficacy and safety can be expected, based on bioequivalence studies.1
CALQUENCE® (acalabrutinib) tablets, for oral use

Initial U.S. Approval: 2017

Brief Summary of Prescribing Information.
For full Prescribing Information consult official package insert.

INDICATIONS AND USAGE

Chronic Lymphocytic Leukemia or Small Lymphocytic Lymphoma
CALQUENCE is indicated for the treatment of adult patients with chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL).

Dosage and Administration

Recommended Dosage

CALQUENCE as Monotherapy
For patients with CLL or SLL, the recommended dosage of CALQUENCE is 100 mg taken orally approximately every 12 hours until disease progression or unacceptable toxicity.

CALQUENCE in Combination with Obinutuzumab

For patients with previously untreated CLL or SLL, the recommended dosage of CALQUENCE is 100 mg taken orally approximately every 12 hours until disease progression or unacceptable toxicity. Start CALQUENCE at Cycle 1 (each cycle is 28 days). Start obinutuzumab at Cycle 2 for a total of 6 cycles and refer to the obinutuzumab prescribing information for recommended dosing. Administer CALQUENCE prior to obinutuzumab when given on the same day.

Advised patients to swallow tablet whole with water. Advise patients not to chew, crush, dissolve, or cut the tablets. CALQUENCE may be taken with or without food. If a dose of CALQUENCE is missed by more than 3 hours, it should be skipped and the next dose should be taken at its regularly scheduled time. Extra tablets of CALQUENCE should not be taken to make up for a missed dose.

Recommended Dosage for Drug Interactions

Dosage Modifications for Use with CYP3A Inhibitors or Inducers

These are described in Table 1 (see Drug Interactions (7) in the full Prescribing Information).

Table 1: Recommended Dosage Modifications for Use with CYP3A Inhibitors or Inducers

<table>
<thead>
<tr>
<th>CYP3A Inhibitor</th>
<th>CYP3A Inducer</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Strong CYP3A</strong></td>
<td></td>
</tr>
<tr>
<td>Inhibitor</td>
<td>Reduces CALQUENCE by approximately 12 hours.</td>
</tr>
<tr>
<td>Moderate CYP3A</td>
<td>Reduces CALQUENCE by 100 mg every 12 hours.</td>
</tr>
<tr>
<td>Inducer</td>
<td>Reduces CALQUENCE by approximately 12 hours.</td>
</tr>
</tbody>
</table>

Dosage Modifications for Adverse Reactions

Recommended dosage modifications of CALQUENCE for Grade 3 or greater adverse reactions are provided in Table 2.

Table 2: Recommended Dosage Modifications for Adverse Reactions

<table>
<thead>
<tr>
<th>Event</th>
<th>Adverse Reaction Occurrence</th>
<th>Dosage Modification</th>
</tr>
</thead>
<tbody>
<tr>
<td>First and Second</td>
<td>Interrupt CALQUENCE</td>
<td>Decrease CALQUENCE by 200 mg approximately every 12 hours.</td>
</tr>
<tr>
<td>Third</td>
<td>Interrupt CALQUENCE</td>
<td>Decrease CALQUENCE by 100 mg every 12 hours.</td>
</tr>
<tr>
<td>Fourth</td>
<td>Discontinue CALQUENCE</td>
<td>Discontinue CALQUENCE.</td>
</tr>
</tbody>
</table>

Adverse reactions graded by the National Cancer Institute Common Terminology Criteria for Adverse Events (NCI CTCAE).

Refer to the obinutuzumab prescribing information for management of obinutuzumab toxicities.

CONTRAINDICATIONS

None.

WARNINGS AND PRECAUTIONS

Serious and Opportunistic Infections

Fatal and serious infections, including opportunistic infections, have occurred in patients with hematologic malignancies treated with CALQUENCE.

Serious or Grade 3 or higher infections (bacterial, viral, or fungal) occurred in 19% of 1029 patients exposed to CALQUENCE in clinical trials, most often due to respiratory tract infections (11% of all patients, including pneumonia) (see Overall Adverse Reactions (6.1) in the full Prescribing Information). The infections predominantly occurred in the absence of Grade 3 or 4 neutropenia, with neutropenic infection reported in 1.9% of all patients. Opportunistic infections in recipients of CALQUENCE and obinutuzumab in combination were not limited to, but included, viral or fungal reactivation, fungal pneumonias, Pneumocystis jirovecii pneumonia, Epstein-Barr virus reactivation, cytomegalovirus, and progressive multifocal leukoencephalopathy (PML). Consider prophylaxis in patients who are at increased risk for opportunistic infections. Monitor patients for signs and symptoms of infection and treat promptly.

Hemorrhage

Fatal and serious hemorrhage events have occurred in patients with hematologic malignancies treated with CALQUENCE. Major hemorrhage (serious or Grade 3 or 4 pericardial or central nervous system bleeding) occurred in 3.0% of patients, with fatal hemorrhage occurring in 0.1% of 1029 patients exposed to CALQUENCE in clinical trials. Bleeding events of any grade, excluding bruising and petechiae, occurred in 25% of patients with CALQUENCE (see Adverse Reactions (6.1) in the full Prescribing Information).

Avoid co-administration.

Use of antithrombotic agents concomitantly with CALQUENCE may further increase the risk of hemorrhage. In clinical trials, major hemorrhage occurred in 2.7% of patients taking CALQUENCE without antithrombotic agents and 3.6% of patients taking CALQUENCE with antithrombotic agents. Consider the risks and benefits of antithrombotic agents when co-administered with CALQUENCE. Monitor patients for signs of bleeding.

Consider the benefit-risk of withholding CALQUENCE for 3 to 7 days prior to pre- or post-surgery depending upon the type of surgery and the risk of bleeding.

Cytopenias

Grade 3 or 4 cytopenias, including neutropenia (23%), anemia (8%), thrombocytopenia (7%), and lymphopenia (7%), developed in patients with CLL from two randomized controlled clinical trials identified in the ELEVATE-TN trial. Grade 4 neutropenia developed in 12% of patients (see Adverse Reactions (6.1) in the full Prescribing Information). Monitor complete blood counts regularly during treatment. Interrupt treatment, reduce the dose, or discontinue treatment as warranted (see Dosage and Administration (2.3) in the full Prescribing Information).

Secondary Primary Malignancies

Second primary malignancies, including skin cancers and other solid tumors, occurred in 12% of 1029 patients exposed to CALQUENCE in clinical trials (see Adverse Reactions (6.1) in the full Prescribing Information). The most frequent second primary malignancy was skin cancer, reported in 6% of patients. Monitor patients for skin cancers and advise protection from sun exposure.

Atrial Fibrillation and Flutter

Grade 3 atrial fibrillation or flutter occurred in 1.1% of 1029 patients treated with CALQUENCE, with all grades of atrial fibrillation or flutter occurring in 1.9% of 1029 patients treated with CALQUENCE. In clinical trials, most often due to events of pneumonia (2.8% to 7%).

In the CALQUENCE+G arm, adverse reactions led to treatment discontinuation in 11% of patients and a dose reduction of CALQUENCE in 7% of patients. In the CALQUENCE+monotherapy arm, adverse reactions led to discontinuation in 10% and dose reduction in 4% of patients.

Tables 5 and 6 present adverse reactions and laboratory abnormalities identified in the ELEVATE-TN trial.

Table 3: Common Adverse Reactions (≥ 15% Any Grade) in Patients with CLL (ELEVATE-TN)

<table>
<thead>
<tr>
<th>Body System</th>
<th>Adverse Reaction</th>
<th>All Grades (%)*</th>
<th>Grade ≥ 3 (%)*</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Infections</strong></td>
<td><strong>Infection</strong></td>
<td>89</td>
<td>29</td>
</tr>
<tr>
<td><strong>Upper respiratory tract infection</strong></td>
<td>39</td>
<td>2.8</td>
<td>35</td>
</tr>
<tr>
<td><strong>Lower respiratory tract infection</strong></td>
<td>24</td>
<td>8</td>
<td>18</td>
</tr>
<tr>
<td><strong>Primary tract infection</strong></td>
<td>15</td>
<td>1.7</td>
<td>15</td>
</tr>
<tr>
<td><strong>Blood and lymphatic system disorders</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Neutropenia</strong></td>
<td>53</td>
<td>13</td>
<td>53</td>
</tr>
<tr>
<td><strong>Anemia</strong></td>
<td>52</td>
<td>12</td>
<td>53</td>
</tr>
<tr>
<td><strong>Thrombocytopenia</strong></td>
<td>51</td>
<td>12</td>
<td>32</td>
</tr>
<tr>
<td><strong>Lymphocytosis</strong></td>
<td>12</td>
<td>11</td>
<td>16</td>
</tr>
<tr>
<td><strong>Nervous system disorders</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Headache</strong></td>
<td>40</td>
<td>1.1</td>
<td>39</td>
</tr>
<tr>
<td><strong>Dizziness</strong></td>
<td>20</td>
<td>0</td>
<td>12</td>
</tr>
<tr>
<td><strong>Gastrointestinal disorders</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Diarrhea</strong></td>
<td>39</td>
<td>4.5</td>
<td>35</td>
</tr>
<tr>
<td><strong>Nausea</strong></td>
<td>20</td>
<td>0.2</td>
<td>22</td>
</tr>
<tr>
<td><strong>Musculoskeletal and connective tissue disorders</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Musculoskeletal pain</strong></td>
<td>37</td>
<td>2</td>
<td>32</td>
</tr>
<tr>
<td><strong>Arthralgia</strong></td>
<td>22</td>
<td>11</td>
<td>16</td>
</tr>
<tr>
<td><strong>Vascular disorders</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Hemorrhage</strong></td>
<td>20</td>
<td>1.1</td>
<td>19</td>
</tr>
</tbody>
</table>

* Percentages may not add up to 100 due to rounding.
CALQUENCE® (acalabrutinib) tablets, for oral use

1 Includes upper respiratory tract infection, nasopharyngitis and sinusitis
2 Includes pneumonia, lower respiratory tract infection, bronchitis, bronchiolitis, tracheitis, lung infection
3 Derived from adverse reaction and laboratory data
4 Includes neutrophilia, neutrophil count decreased, and related laboratory data
5 Includes anemia, reticulocyte count decreased, and related laboratory data
6 Includes thrombocytopenia, platelet count decreased, and related laboratory data
7 Includes lymphopenia, lymphocyte count increased, and related laboratory data
8 Includes back pain, bone pain, muscularkeletal chest pain, muscularkeletal pain, muscularkeletal discomfort, muscle pain, back pain, pain in extremity and spinal pain
9 Includes asthma, fatigue, and lethargy
10 Includes rash, dermatitis, and other related terms
11 Includes anemia, red blood cell count decreased, and related laboratory data
12 Includes hemorrhage, hematoma, hemoptysis, hematuria, menorrhagia, hemarthrosis, and ophthalmia

Other clinically relevant adverse reactions (all grades incidence < 15%) in recipients of CALQUENCE (CALQUENCE in combination with obinutuzumab and monotherapy) included:
- Nephrotoxicity: second primary malignancy (10%), non-melanoma skin cancer (5%)
- Cardiac disorders: atrial fibrillation or flutter (3.6%), hypertension (5%)
- Infection: herpesvirus infection (5%)

Table 6: Select Non-Hematologic Laboratory Abnormalities (≥ 15% Any Grade), New or Worse from Baseline in Patients Receiving CALQUENCE (ELEVATE-IV/TN)

Table 7: Common Adverse Reactions (≥ 15% Any Grade) with CALQUENCE in Patients with CLL (ASCEND)

Table 8: Select Non-Hematologic Laboratory Abnormalities (≥ 10% Any Grade), New or Worse from Baseline in Patients Receiving CALQUENCE (ASCEND)

* Per NCI CTCAE version 4.03
† Includes electrolytes
‡ Includes hemorrhage, hematoma, hemoptysis, hematuria, menorrhagia, hemarthrosis, and ophthalmia
§ Includes upper respiratory tract infection, rhinitis and nasopharyngitis

Other clinically relevant adverse reactions (all grades incidence < 15%) in recipients of CALQUENCE included:
- Skin and subcutaneous disorders: bruising (10%), rash (9%)
- Nephrotoxicity: second primary malignancy (12%), non-melanoma skin cancer (6%)
- Musculoskeletal and connective tissue disorders: arthritis/arthralgia (8%)
- Cardiovascular disorders: atrial fibrillation or flutter (5%), hypertension (3.2%)
- Infection: herpesvirus infection (4.5%)

Table 9: Select Non-Hematologic Laboratory Abnormalities (≥ 10% Any Grade), New or Worse from Baseline in Patients Receiving CALQUENCE plus rituximab (≥ 10% Any Grade), New or Worse from Baseline in Patients Receiving CALQUENCE (ASCEND)

<table>
<thead>
<tr>
<th>Laboratory Abnormality</th>
<th>CALQUENCE plus Obinutuzumab N=178</th>
<th>CALQUENCE plus Monotherapy N=179</th>
<th>CALQUENCE plus Chlorambucil N=179</th>
</tr>
</thead>
<tbody>
<tr>
<td>ALT increase</td>
<td>29 29</td>
<td>22 22</td>
<td>97 97</td>
</tr>
<tr>
<td>AST increase</td>
<td>38 5 15</td>
<td>7 6 0</td>
<td>6 8 0</td>
</tr>
<tr>
<td>Bilirubin increase</td>
<td>13 6 0</td>
<td>15 6 0</td>
<td>11 0 0</td>
</tr>
</tbody>
</table>

* Per NCI CTCAE version 4.03
† Includes adverse reactions involving infection or fibrosis/neoplasia
‡ Includes 1 fatal case in the CALQUENCE monotherapy arm and 1 fatal case in the idelalisib plus rituximab arm
§ Includes upper respiratory tract infection, rhinitis and nasopharyngitis

In recipients of CALQUENCE, permanent discontinuation due to an adverse reaction occurred in 10% of patients. The estimated background risk of major birth defects and miscarriage for the indicated population is unknown. All pregnancies have a background risk of birth defect, loss, or other adverse outcomes. In the general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2% to 4% and 15 to 20%, respectively.

Data
Animal Data
In a combined fertility and embryo-fetal development study in female rats, acalabrutinib was administered orally at doses up to 210 mg/kg/day starting 14 days prior to mating through gestational day (GD) 17. No effects on embryo-fetal development and survival were observed. The AUC at 200 mg/kg/day in pregnant rats was approximately 9 times the AUC in patients at the recommended dose of 100 mg approximately every 12 hours. The presence of acalabrutinib and its active metabolite were confirmed in fetal rat plasma.

In an embryo-fetal development study in rats, pregnant animals were administered acalabrutinib orally at doses up to 200 mg/kg/day during the period of organogenesis (from GD 6-18). Administration of acalabrutinib at doses ≥ 100 mg/kg/day produced maternal toxicity and 100 mg/kg/day resulted in decreased fetal body weights and delayed skeletal ossification. The AUC at 100 mg/kg/day in pregnant rabbits was approximately 2 times the AUC in patients at 100 mg approximately every 12 hours. In a pre- and postnatal development study in rats, acalabrutinib was administered orally to pregnant animals during organogenesis, parturition and lactation, at doses of 50, 100, and 150 mg/kg/day. Dystocia (prolonged or difficult labor) and mortality of offspring were observed at doses ≥ 100 mg/kg/day. The AUC at 100 mg/kg/day was approximately 2 times the AUC in rats at 100 mg approximately every 12 hours. Underdeveloped renal papilla was also observed in 51 generation offspring at 150 mg/kg/day with an AUC approximately 5 times the AUC in patients at 100 mg approximately every 12 hours.

Lactation Risk Summary
No data are available regarding the presence of acalabrutinib or its active metabolite in human milk, its effects on the breastfed child, or on milk production. Acalabrutinib and its active metabolite were present in the milk of lactating rats when rats were treated with acalabrutinib in a breed in child from CALQUENCE, advise lactating women not to breastfeed while taking CALQUENCE for 1 or 2 weeks after the last dose. Females and Males of Reproductive Potential CALQUENCE may cause embryo-fetal harm and dystocia when administered to pregnant women. Use in Specific Populations (8.1) in the full Prescribing Information.

Pregnancy Testing
Pregnancy testing is recommended for females of reproductive potential prior to initiating CALQUENCE therapy.

Contraception
Advise female patients of reproductive potential to use effective contraception during treatment with CALQUENCE and for 1 week following the last dose of CALQUENCE. If this drug is used during pregnancy, or if the patient becomes pregnant while taking this drug, the patient should be informed of the potential hazard to a fetus.

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

Geriatric Use
Of the 929 patients with CLL or MCL in clinical trials of CALQUENCE, 68% were 65 years of age or older and 25% were ≥ 75 years of age. Among patients 65 years of age or older, 59% had Grade 3 or higher adverse reactions and 39% had serious adverse reactions. Among patients younger than age 65, 45% had Grade 3 or higher adverse reactions and 25% had serious adverse reactions. No clinically relevant differences in efficacy were observed between patients ≥ 65 years and younger.

Hepatic Impairment
Avoid use of CALQUENCE in patients with severe hepatic impairment (Child-Pugh class C). No dosage adjustment of CALQUENCE is recommended in patients with mild (Child-Pugh class A) or moderate (Child-Pugh class B) hepatic impairment. The safety of CALQUENCE has not been evaluated in patients with moderate or severe hepatic impairment (see Clinical Pharmacology (12.3) in the full Prescribing Information).

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Consider an Investigational Trial for Patients with

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MK-2140-003
• Evaluating MK-2140, an investigational antibody-drug conjugate (ADC), in combination with chemotherapy, for relapsed/refractory diffuse large B-cell lymphoma (DLBCL)

MK-2140-004
• Evaluating MK-2140, an investigational antibody-drug conjugate (ADC) for patients with relapsed/refractory diffuse large B-cell lymphoma (DLBCL) who have not responded to other treatment options

MK-2140-006
• Evaluating MK-2140, an investigational antibody-drug conjugate (ADC), as a monotherapy and in combination for participants with aggressive and indolent B-cell malignancies

MK-1026-003
• Evaluating MK-1026, an investigational inhibitor of Bruton’s tyrosine kinase (BTK), in multiple relapsed/refractory hematologic malignancies (including CLL/SLL, Richter’s transformation, marginal zone lymphoma [MZL], MCL, FL, and Waldenström’s macroglobulinemia [WM])

MK-1026-008
• Evaluating MK-1026, an investigational inhibitor of Bruton’s tyrosine kinase (BTK), versus chemoimmunotherapy for previously untreated chronic lymphocytic leukemia/small lymphocytic lymphoma without TP53 aberrations

MK-1026-010
• Evaluating MK-1026 (an investigational inhibitor of Bruton’s tyrosine kinase [BTK]) plus venetoclax, versus venetoclax plus rituximab, in participants with relapsed/refractory chronic lymphocytic leukemia/small lymphocytic lymphoma following at least 1 prior therapy

MK-3475-667
• Evaluating pembrolizumab in children and young adults with newly diagnosed classical Hodgkin lymphoma with inadequate (slow early) response to frontline chemotherapy

MK-4280-003
• Evaluating a combination of MK-4280, an investigational lymphocyte activation gene-3 (LAG3) inhibitor, and pembrolizumab in participants with hematologic malignancies

MK-4280A-008
• Evaluating MK-4280A, an investigational coformulation of MK-4280 (an investigational lymphocyte activation gene-3 [LAG3] inhibitor) plus pembrolizumab versus physician’s choice chemotherapy in PD-(L)1-refractory, relapsed, or refractory classical Hodgkin lymphoma
Normally, macrophages use phagocytosis to clean up abnormal cells, guided by “eat me” signals.\textsuperscript{1,2}

However, in higher-risk MDS, abnormal cells can protect themselves from phagocytosis by expressing “don’t eat me” signals, such as CD47.\textsuperscript{1,2}

Visit MDSinFocus.com to learn more about Gilead and the investigation.

For 40 years, the Cancer Support Community (CSC) has been a relentless ally for anyone impacted by cancer, delivering more than $50 million in free support services to patients and families, in-person, online, or over our toll-free helpline. CSC helps individuals manage the realities of this disruptive disease and get back to living.

CSC produces award-winning educational resources including booklets, worksheets, videos, and podcasts - all of which are available for free.

YOUR PARTNER IN PATIENT CARE

RESOURCES FOR PROFESSIONALS

- Scientific Symposium
- Satellite Symposia: ASH and ONS
- Community Bone Marrow Failure Disease Symposia
- Free Online CME Programs at: www.aamds.org/CME
- Research Grants
- Tool Kits: MDS, PNH & Aplastic Anemia

RESOURCES FOR YOUR PATIENTS

- Patient and Family Conferences
- Patient Education Webinars
- Podcasts for Patients
- Patient Education Materials
- Patient HelpLine
- Peer Support Network
- Patient Support Groups

For more information, contact Alice Houk
Senior Director of Patient and Professional Services, houk@aamds.org

www.aamds.org  #aamdsif

Visit Us at Our Virtual Booth
Driving groundbreaking research.
Improving lives.

The MPN Research Foundation’s mission is to help people with an MPN live a better quality of life as we work toward answers to prevention, progression and a cure for polycythemia vera (PV), essential thrombocythemia (ET) and myelofibrosis (MF) – blood cancers collectively known as myeloproliferative neoplasms (MPNs).

To learn more, visit our website mpnresearchfoundation.org

For 21 years the MPN Research Foundation has delivered on a bold commitment to fund global pioneers studying innovative approaches to prevention, halting progression, and improved quality of life for people living with an MPN. Convening patients and caregivers, researchers and clinicians, biopharmaceutical industry leaders and advocates, around the world, together we are conquering MPNs. See our IMPACT@MPNRF mpnresearchfoundation.org/impact/

The Myelodysplastic Syndromes (MDS) Foundation, Inc. was established by an international group of physicians and researchers to provide an ongoing exchange of information relating to MDS.

Until the Foundation was set up, no formal working group had been devoted to MDS. Since its inception, we have conducted 15 international symposia in Austria, England, the United States (Chicago, Washington, DC), Spain (Barcelona, Valencia), Czech Republic, Sweden, France, Japan, Italy, Greece, Scotland, and Germany. The 16th International Congress will be held in Toronto, Canada on September 23-26, 2021.

A major MDS Foundation effort is our international information network. This network provides patients with referrals to Centers of Excellence, contact names for available clinical trials, sharing of new research and treatment options between physicians, and extension of educational support to physicians, nurses, pharmacists and patients.

In response to the needs expressed by patients, families, and healthcare professionals, we have established patient advocacy groups, research funding, and professional educational initiatives.

The MDS Foundation is a publicly supported organization, exempt from federal income tax under section 501(C)(3) of the IRS code.

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Learn more about The Myelodysplastic Syndromes Foundation, Inc. and find additional resources here: www.mds-foundation.org
Driving groundbreaking research.
Improving lives.
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- For Young Adults
- For Seniors

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We’re not waiting for a cure. Together, we’re accelerating one.

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A blood cancer diagnosis can be overwhelming for your patients. Blood cancer patients, including those with leukemia, lymphoma and myeloma, can find hope, education, guidance and support from The Leukemia & Lymphoma Society (LLS).

Our Information Specialists complement the care you provide with FREE, in-depth personalized services that connect patients to financial assistance, patient education (including booklets, podcasts and webinars), online and in-person support, and the LLS Clinical Trial Support Center for assistance with clinical trials.

Patients and families can contact us at 800.955.4572 or go to www.LLS.org/patient-support.
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**Hematologic Malignancies™ 2023 Annual Congress:**
Friday, September 22, 2023 – Saturday, September 23, 2023

Pre-Congress Program — Friday, September 22, 2023
NCCN 2023 Nursing Forum: Advancing Oncology Nursing™
Hilton San Francisco Union Square • San Francisco, California

**NCCN.org/conference**

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Virtual attendance available

**Pre-Conference Program — Thursday, March 30, 2023**
NCCN 2023 Nursing Program: Advancing Oncology Nursing™

**NCCN.org/hem**

Friday, March 31, 2023 – Sunday, April 2, 2023

View all upcoming NCCN events at [NCCN.org/events](http://NCCN.org/events).