U.S. FDA Grants BeiGene's BRUKINSA™ (zanubrutinib) Accelerated Approval to Treat Adult Patients with Mantle Cell Lymphoma Who Received at Least One Prior Therapy

- *This marks the first FDA approval for BeiGene*

- *84% of patients taking BRUKINSA achieved an overall response[1]*

- *BRUKINSA is the only FDA-approved BTK inhibitor shown to deliver 100% median occupancy in peripheral blood cells and the only BTK inhibitor with the flexibility to be taken once or twice daily*

CAMBRIDGE, Mass. and BEIJING, China, November 14, 2019 (GLOBE NEWSWIRE) -- BeiGene, Ltd. (NASDAQ: BGNE; HKEX: 06160), a commercial-stage biopharmaceutical company focused on developing and commercializing innovative molecularly-targeted and immuno-oncology drugs for the treatment of cancer, today announced that BRUKINSA™ (zanubrutinib) has received accelerated approval from the United States Food and Drug Administration (FDA) as a treatment for mantle cell lymphoma (MCL) in adult patients who have received at least one prior therapy.[1] BRUKINSA is the first BeiGene-discovered product to be approved, an important milestone toward the company's goal of transforming treatment for cancer patients around the world.

This accelerated approval is based on overall response rate (ORR). Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.

"We are working to improve outcomes for people with cancer worldwide and this approval brings us closer to realizing our mission of bringing the highest quality therapies to patients globally," said John V. Oyler, Chairman, Co-Founder, and CEO of BeiGene. "Today's FDA approval of BRUKINSA, following the previously granted Breakthrough Therapy designation in this indication, validates it as an important treatment option for people with relapsed or refractory MCL. We hope this is the first of many approvals for BRUKINSA as we continue to evaluate its potential in other hematologic cancers."

"BRUKINSA is a BTK inhibitor that was designed to maximize target occupancy and minimize off-target binding. It entered the clinic in 2014 and since that time our broad development program has enrolled more than 1,600 patients globally," said Jane

Huang, M.D., Chief Medical Officer, Hematology at BeiGene. “Today’s accelerated approval is the culmination of many years of effort by the BeiGene team, the dedicated investigators involved in these trials and, most importantly, the patients who participated by enrolling in the clinical trials. We are humbled by the opportunity to develop this therapy and launch it as our first internally discovered and approved cancer treatment.”

“BTK inhibition is an established mode of treatment for patients with MCL, but many patients treated with previously approved BTK inhibitors do not fully respond to BTK therapy or are forced to discontinue treatment early due to side effects. Today we have a new option for our adult patients who have received one prior systemic or targeted therapy and are living with MCL, an aggressive blood cancer that’s often diagnosed at a more advanced stage,” said Luhua (Michael) Wang, M.D., Professor, Department of Lymphoma and Myeloma, Division of Cancer Medicine at The University of Texas MD Anderson Cancer Center, and clinical trial investigator.

“The approval of BRUKINSA as a second line therapy represents an important advancement for the treatment of mantle cell lymphoma,” said Meghan Gutierrez, Chief Executive Officer for the Lymphoma Research Foundation. “Expanded treatment options can transform the patient experience and provide hope to people living with a mantle cell diagnosis.”

The FDA’s approval of BRUKINSA is based on efficacy results from two single-arm clinical trials, with independent review committee (IRC)-assessed ORR per 2014 Lugano Classification as the primary endpoint. Across both trials, BRUKINSA achieved an ORR, which is the sum of complete responses and partial responses, of 84%.

In the multicenter Phase 2 trial of zanubrutinib in patients with relapsed or refractory (R/R) MCL BGB-3111-206 (NCT03206970), the ORR was 84% (95% CI: 74%, 91%), including 59% complete response (FDG-PET scan required) and 24% partial response. In this study, the median duration of response (DOR) was 19.5 months (95%CI: 16.6, NE) and median follow-up time on study was 18.4 months. In the global Phase 1/2 trial BGB-3111-AU-003 (NCT02343120), the ORR was 84% (95% CI: 67%, 95%), including 22% complete response (FDG-PET scan not required) and 62% partial response. In this study, the median DOR was 18.5 months[1] (95% CI:12.6, NE) and median follow-up time on study was 18.8 months.

The most common adverse reactions (> 10%) with BRUKINSA were decreased neutrophil count, decreased platelet count, upper respiratory tract infection, decreased white blood cell count, decreased hemoglobin, rash, bruising, diarrhea, cough,

musculoskeletal pain, pneumonia, urinary tract infection, blood in the urine (hematuria), fatigue, constipation, and hemorrhage. The most frequent serious adverse reactions were pneumonia (11%) and hemorrhage (5%).

Of the 118 patients with MCL treated with BRUKINSA, eight (7%) patients discontinued treatment due to adverse reactions in the trials. The most frequent adverse reaction leading to treatment discontinuation was pneumonia (3.4%). One (0.8%) patient experienced an adverse reaction leading to dose reduction (hepatitis B).

The recommended dose of BRUKINSA is 320 mg, taken orally 160 mg twice daily or 320 mg once daily with or without food. The dose may be adjusted for adverse reactions, and reduced for patients with severe hepatic impairment and certain drug interactions.[1]

BRUKINSA is expected to be available to people in the United States in the coming weeks.

myBeiGene™ Patient Support Program

BeiGene is committed to ensuring that people have access to the medicine and the support needed to have the best possible outcomes and experiences. Coinciding with today's approval, BeiGene is launching myBeiGene™ in the United States to support patients, caregivers, and healthcare providers with access to BRUKINSA. The myBeiGene program goes beyond financial assistance support to provide patients and caregivers with education about their disease and treatment with BRUKINSA, as well provide practical and emotional support by connecting them to third-party resources that can address their individual unique needs. For more information on myBeiGene, please call 1-833-234-4363 or visit BRUKINSA.com.

About Mantle Cell Lymphoma (MCL)

Lymphoma is a diverse group of cancers that originate from B-, T- or NK- cells. MCL is typically an aggressive form of non-Hodgkin's lymphoma (NHL) that arises from B-cells originating in the "mantle zone."[2] In the United States, about 74,200 people will be diagnosed with NHL in 2019,[3] with MCL representing about six percent (about 4,452 cases) of all new cases of NHL.[2] MCL usually has a poor prognosis, with a median survival of three to four years,[4] and it often diagnosed at a later stage of disease.

About BRUKINSA (zanubrutinib)

BRUKINSA is a small molecule inhibitor of Bruton's tyrosine kinase (BTK), discovered by BeiGene scientists, that is currently being evaluated globally in a broad pivotal clinical program as a monotherapy and in combination with other therapies to treat various B-cell malignancies. BRUKINSA was approved by the U.S. FDA to treat adult patients with MCL who have received at least one prior therapy on November 14, 2019.

New Drug Applications (NDAs) in China for relapsed refractory (R/R) MCL and R/R chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) have been accepted by the China National Medical Products Administration (NMPA) and granted priority review and are pending approval.

BRUKINSA is not approved for use outside the United States.

IMPORTANT SAFETY INFORMATION FOR BRUKINSA (ZANUBRUTINIB)

Warnings and Precautions

Hemorrhage

Fatal and serious hemorrhagic events have occurred in patients with hematological malignancies treated with BRUKINSA monotherapy. Grade 3 or higher bleeding events including intracranial and gastrointestinal hemorrhage, hematuria and hemothorax have been reported in 2% of patients treated with BRUKINSA monotherapy. Bleeding events of any grade, including purpura and petechiae, occurred in 50% 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 23% of patients treated with BRUKINSA monotherapy. The most common Grade 3 or higher infection was 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 (27%), thrombocytopenia (10%) and anemia (8%) based on laboratory measurements, were reported in patients treated with BRUKINSA monotherapy.

Monitor complete blood counts during treatment and treat using growth factor or transfusions, as needed.

Second Primary Malignancies

Second primary malignancies, including non-skin carcinoma, have occurred in 9% of patients treated with BRUKINSA monotherapy. The most frequent second primary malignancy was skin cancer (basal cell carcinoma and squamous cell carcinoma of skin), reported in 6% of patients. Advise patients to use sun protection.

Cardiac Arrhythmias

Atrial fibrillation and atrial flutter have occurred in 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 0.6% 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 fetal harm when administered to a pregnant woman. Administration of zanubrutinib to pregnant rats during the period of organogenesis caused embryo-fetal toxicity, including malformations at exposures that were 5 times higher than those reported in patients at the recommended dose of 160 mg twice daily. Advise women to avoid becoming pregnant while taking BRUKINSA and for at least 1 week after the last dose. Advise men to avoid fathering a child during treatment and for at least 1 week after the last dose. If this drug is used during pregnancy, or if the patient becomes pregnant while taking this drug, the patient should be apprised of the potential hazard to a fetus.

Adverse Reactions

The most common adverse reactions in > 10% of patients who received BRUKINSA were neutrophil count decreased (53%), platelet count decreased (39%), upper respiratory tract infection (38%), white blood cell count decreased (30%), hemoglobin decreased (29%), rash (25%), bruising (23%), diarrhea (20%), cough (20%), musculoskeletal pain (19%), pneumonia (18%), urinary tract infection (13%), hematuria

(12%), fatigue (11%), constipation (11%), and hemorrhage (10%). The most frequent serious adverse reactions were pneumonia (11%) and hemorrhage (5%).

Drug Interactions

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

CYP3A Inducers: Avoid coadministration 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.

INDICATION

BRUKINSA is a kinase 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 a confirmatory trial.

Please see full Prescribing Information at beigene.com/PDF/BRUKINSAUSPI.pdf and Patient Information at beigene.com/PDF/BRUKINSAUSPPI.pdf

About the Zanubrutinib Clinical Trial Program

Clinical trials of zanubrutinib include:

- Fully-enrolled Phase 3 ASPEN clinical trial in patients with Waldenström macroglobulinemia (WM) comparing zanubrutinib to ibrutinib (NCT03053440), currently the only approved BTK inhibitor for WM;
- Phase 3 SEQUOIA trial comparing zanubrutinib with bendamustine plus rituximab in patients with treatment-naive (TN) chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) (NCT03336333);
- Phase 3 ALPINE trial comparing zanubrutinib to ibrutinib in patients with relapsed/refractory (R/R) CLL/SLL (NCT03734016);
- Phase 2 trial in combination with GAZYVA® (obinutuzumab) in patients with R/R follicular lymphoma (FL) (NCT03332017);

- Phase 3 trial comparing zanubrutinib and rituximab to bendamustine and rituximab in patients with untreated MCL (NCT04002297);
- Phase 2 MAGNOLIA trial in patients with R/R marginal zone lymphoma (MZL) (NCT03846427);
- Phase 2 ROSEWOOD trial (NCT03332017) in China comparing obinutuzumab and zanubrutinib vs obinutuzumab alone in treating patients with R/R FL;
- Completed Phase 2 trials in patients with R/R MCL (NCT03206970) and R/R CLL/SLL (NCT03206918); and
- Completed enrollment in Phase 2 clinical trial in patients with WM (NCT03332173).

About BeiGene

BeiGene is a global, commercial-stage, research-based biotechnology company focused on molecularly-targeted and immuno-oncology cancer therapeutics. With a team of over 3,000 employees in the United States, China, Australia, and Europe; BeiGene is advancing a pipeline consisting of novel oral small molecules and monoclonal antibodies for cancer. BeiGene is also working to create combination solutions aimed to have both a meaningful and lasting impact on cancer patients. In the United States, BeiGene markets and distributes BRUKINSA™ (zanubrutinib) and in China, the Company markets ABRAXANE® (nanoparticle albumin–bound paclitaxel), REVLIMID® (lenalidomide), and VIDAZA® (azacitidine) under a license from Celgene Corporation.[5]

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 and other federal securities laws, including statements regarding BeiGene's plans and expectations for the commercialization of BRUKINSA, the potential implications of clinical data for patients, BeiGene's further advancement of, and anticipated clinical development, regulatory milestones and commercialization of BRUKINSA. Actual results may differ materially from those indicated in the forward-looking statements as a result of various important factors, including BeiGene's ability to demonstrate the efficacy and safety of its drug candidates; the clinical results for its drug candidates, which may not support further development or marketing approval; actions of regulatory agencies, which may affect

the initiation, timing and progress of clinical trials and marketing approval; BeiGene's ability to achieve commercial success for its marketed products and drug candidates, if approved; BeiGene's ability to obtain and maintain protection of intellectual property for its technology and drugs; BeiGene's reliance on third parties to conduct drug development, manufacturing and other services; BeiGene's limited operating history and BeiGene's ability to obtain additional funding for operations and to complete the development and commercialization of its drug candidates, as well as those risks more fully discussed in the section entitled "Risk Factors" in BeiGene's most recent quarterly report on Form 10-Q, as well as discussions of potential risks, uncertainties, and other important factors in BeiGene's subsequent filings with the U.S. Securities and Exchange Commission. All information in this press release is as of the date of this press release, and BeiGene undertakes no duty to update such information unless required by law.

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[1] BRUKINSA (zanubrutinib) Prescribing Information. beigene.com/PDF/BRUKINSAUSPI.pdf. BeiGene, Ltd; November 14, 2019.

[2] https://www.lls.org/sites/default/files/file_assets/FS4_MCL_Facts_2018-final.pdf

[3] https://www.cancer.org/cancer/non-hodgkin-lymphoma/about/key-statistics.html

[4] Philip J. Bierman, James O. Armitage, in Goldman's Cecil Medicine (Twenty Fourth Edition), 2012.

[5] ABRAXANE®, REVLIMID® and VIDAZA® are registered trademarks of Celgene Corporation.