BeiGene Clinical Data Presentations at 2022 ASCO Annual Meeting Demonstrate Mature and Growing Oncology Portfolio

- *Long-term follow-up data from the Phase 3 ASPEN head-to-head trial of zanubrutinib versus ibrutinib in Waldenström macroglobulinemia*
- *Results from the Phase 2 ROSEWOOD trial of zanubrutinib plus obinutuzumab versus obinutuzumab monotherapy in follicular lymphoma*

CAMBRIDGE, Mass., BASEL, Switzerland & BEIJING, China — May 26, 2022 — BeiGene (NASDAQ: BGNE; HKEX: 06160; SSE: 688235), a global, science-driven biotechnology company focused on developing innovative and affordable medicines to improve treatment outcomes and access for patients worldwide, will present data from its broad solid tumor and hematology portfolios in eight presentations at the upcoming American Society of Cancer Oncology (ASCO) Annual Meeting being held in Chicago from June 3-7, 2022. Highlights include new clinical data for its BTK-inhibitor zanubrutinib (BRUKINSA®):

- Long-term safety and efficacy results from the Phase 3 ASPEN trial of BRUKINSA versus ibrutinib in patients with Waldenström macroglobulinemia, with median follow up of 43 months
- Primary analysis from the Phase 2 ROSEWOOD trial of zanubrutinib plus obinutuzumab versus obinutuzumab monotherapy in patients with relapsed or refractory follicular lymphoma

“Waldenström macroglobulinemia is a chronic, indolent condition with median survival of 14 to 16 years, so it is important to understand the long-term profile for treatments. The durable response and continued safety advantage seen in the long-term follow up period of the ASPEN trial supports our confidence in the compelling safety and efficacy profile for BRUKINSA,” said Lai Wang, Ph.D., Global Head of R&D at BeiGene. “We continue to explore zanubrutinib in additional indications that may lack tolerable and effective treatment options and we are encouraged by the results from our Phase 2 ROSEWOOD study in a high-risk, relapsed/refractory follicular lymphoma population.”

In addition to results from BRUKINSA trials, the company will also present posters from its early development pipeline and results from the Phase 3 RATIONALE-309 trial of tislelizumab in the Rapid Abstract Update session on June 5th. RATIONALE 309 is a Phase 3 trial of tislelizumab, a humanized anti-PD-1 monoclonal antibody, in combination with chemotherapy versus chemotherapy plus placebo as a first-line treatment for patients with recurrent or metastatic nasopharyngeal cancer. These results were initially presented at the virtual ASCO Plenary Series on April 19, 2022: BeiGene Presents Updated Results from Phase 3 RATIONALE-309

For more information on BeiGene’s clinical program and company updates, please visit BeiGene’s virtual ASCO booth: www.BeiGenevirtualexperience.com

----------**ASPEN and ROSEWOOD details**----------

ASPEN: Long-term follow-up results of a Phase 3 randomized trial of zanubrutinib versus ibrutinib in patients with Waldenström macroglobulinemia (WM)
Abstract Number: 7521

With a median follow-up of 43 months, BRUKINSA continued to demonstrate clinically meaningful efficacy and a tolerable safety profile in patients with WM.

- Exploratory analyses showed a consistent trend of deeper, earlier, and more durable responses (CR+VGPR) compared with ibrutinib over time
- Median time to CR+VGPR was shorter for zanubrutinib: 6.7 months (range, 1.9-42.0) vs ibrutinib: 16.6 months (range, 2.0-49.9)
- Over the follow-up period, patients receiving with zanubrutinib had fewer adverse events leading to death, treatment discontinuation, and dose reduction as compared with ibrutinib
- The prevalence of atrial fibrillation, hypertension, and bleeding were lower in the zanubrutinib arm at all time intervals; Neutropenia occurred early, and prevalence decreased over time for patients receiving zanubrutinib

Zanubrutinib plus obinutuzumab (ZO) versus obinutuzumab (O) monotherapy in patients (pts) with relapsed or refractory (R/R) follicular lymphoma (FL): primary analysis of the Phase 2 randomized ROSEWOOD trial
Abstract Number: 7510

The ROSEWOOD trial met its primary endpoint with a 68.3% overall response rate (ORR) in the zanubrutinib plus obinutuzumab arm versus 45.8% in the obinutuzumab arm (p = 0.0017) and median follow-up of 12.5 months. Zanubrutinib plus obinutuzumab was generally well-tolerated, with safety results consistent with previous studies of both medicines.

- Zanubrutinib plus obinutuzumab was associated with a deep and durable response, with a complete response (CR) rate of 37.2% compared to 19.4% for obinutuzumab alone; 18-month duration of response rate was 70.9% in the zanubrutinib plus obinutuzumab arm versus 54.6% in the obinutuzumab arm
- Time to next anti-lymphoma treatment was significantly prolonged in the zanubrutinib plus obinutuzumab arm (HR 0.37; p ,0.0001)
- Median progression-free survival was 27.4 months in the zanubrutinib plus obinutuzumab arm compared to 11.2 months in the obinutuzumab arm (HR: 0.51 [95% CI, 0.32, -0.81],)
- The most common any-grade and grade ≥ 3 toxicities in the zanubrutinib plus obinutuzumab arm were hematologic toxicities, and other toxicities were similar between the two arms
- Infusion-related reactions were more frequent in the obinutuzumab monotherapy arm

About ASPEN
ASPEN is a randomized, global, open-label, multi-center Phase 3 study comparing BRUKINSA to ibrutinib in patients with relapsed or refractory (R/R) or treatment-naive Waldenström macroglobulinemia. The primary endpoint was proportion of patients achieving complete response or very good partial response (CR+VGPR). Patients with MYD88 mutations were assigned to cohort 1 and randomized 1:1 to receive BRUKINSA 160 mg twice daily or ibrutinib 420 mg once daily. Patients without MYD88 mutations were assigned to cohort 2 and received BRUKINSA160 mg twice daily. A total of 229 patients were enrolled in the trial, with 130 patients receiving BRUKINSA and 99 patients receiving ibrutinib.

As assessed by an independent review committee based on the modified Sixth International Workshop on Waldenström's Macroglobulinemia (IWWM-6) response criteria (Treon 2015), the combined rate of CR and VGPR in the overall intent-to-treat population was 28% with BRUKINSA (95% CI: 20, 38), compared to 19% with ibrutinib (95% CI: 12, 28). While this difference was not statistically significant (p=0.09), BRUKINSA did achieve numerically higher VGPR rates and trends towards increased depth of response.

In the ASPEN trial, BRUKINSA demonstrated a more favorable safety profile compared to ibrutinib with lower frequency of certain adverse events, including atrial fibrillation or flutter (2% vs. 15%) and major hemorrhage (6% vs. 9%). Of the 101 patients with WM treated with BRUKINSA, 4% of patients discontinued due to adverse events, and adverse events leading to dose reduction occurred in 14% of patients.

About ROSEWOOD
ROSEWOOD is a randomized, open-label, Phase 2 study comparing BRUKINSA plus obinutuzumab to obinutuzumab alone in patients with R/R FL who have received two or more lines of therapy. The primary endpoint was overall response rate (ORR) assessed by independent central review (ICR) according to the Lugano classification. Select secondary endpoints include: investigator-assessed ORR, ICR-reviewed and investigator-assed duration of response and progression-free survival, overall survival, ICR- and investigator-assessed CR and complete metabolic response rate. A total of 217 patients were enrolled in the trial, with 145 patients receiving BRUKINSA plus obinutuzumab and 72 patients receiving obinutuzumab.

About BRUKINSA
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 clinical program as a monotherapy and in combination with other therapies to treat various B-cell malignancies. Because new BTK is continuously synthesized, BRUKINSA was specifically designed to deliver complete and sustained inhibition of the BTK protein by optimizing bioavailability, half-life, and selectivity. With differentiated pharmacokinetics compared to other approved BTK inhibitors, BRUKINSA has been demonstrated to inhibit the proliferation of malignant B cells within a number of disease relevant tissues.

BRUKINSA is supported by a broad clinical program which includes more than 3,900 subjects in 35 trials across 28 markets. To date, BRUKINSA has received more than 20 approvals covering more than 40 countries and regions, including the United States, China, the EU and Great Britain, Canada, Australia and additional international markets. Currently, more than 40 additional regulatory submissions are in review around the world.

About Tislelizumab

Tislelizumab is an anti-programmed death receptor-1 (PD-1) inhibitor designed to help aid the body's immune cells to detect and fight tumors. Tislelizumab, a humanized monoclonal antibody, is specifically designed to minimize binding to FcγR on macrophages. In pre-clinical studies, binding to FcγR on macrophages has been shown to compromise the anti-tumor activity of PD-1 antibodies through activation of antibody-dependent macrophage-mediated killing of T effector cells.

Tislelizumab is the first drug from BeiGene's immuno-oncology biologics program and is being developed internationally as a monotherapy and in combination with other therapies for the treatment of a broad array of both solid tumor and hematologic cancers. BeiGene has initiated or completed more than 20 potentially registration-enabling clinical trials in 35 countries and regions, including 17 Phase 3 trials and four pivotal Phase 2 trials. More information on the clinical trial program for tislelizumab can be found at: https://www.beigene.com/en-us/science-and-product-portfolio/pipeline

Tislelizumab is approved by the China National Medical Products Administration (NMPA) as a treatment for eight indications, including multiple approvals in non-small cell lung cancer (NSCLC). Tislelizumab is currently in regulatory review in one additional indication in first line recurrent/metastatic nasopharyngeal cancer in China; as a potential treatment for unresectable recurrent locally advanced or metastatic esophageal squamous cell carcinoma (ESCC) after prior systemic therapy in the U.S.; and in NSCLC and ESCC in Europe. In January 2021, BeiGene partnered with Novartis to accelerate the clinical development and marketing of tislelizumab in North America, Europe and Japan.

BeiGene Oncology

BeiGene is committed to advancing best- and first-in-class clinical candidates internally or with like-minded partners to develop impactful and affordable medicines for patients across the globe. We have a growing R&D and medical affairs team of approximately 2,900 colleagues dedicated to advancing more than 100 clinical trials that have involved more than 16,000 subjects. Our expansive portfolio is directed predominantly by our internal colleagues supporting clinical trials in more than 45 geographies. Hematology-oncology and solid tumor targeted therapies and immuno-oncology are key focus areas for the Company, with both mono- and combination therapies prioritized in our research and development. BeiGene currently has three approved medicines discovered and developed in our own labs: BTK inhibitor BRUKINSA® in the U.S., China, the European Union, Great Britain, Canada, Australia, and additional international markets; and the non-FC-gamma receptor binding anti-PD-1 antibody tislelizumab as well as the PARP inhibitor pamiparib in China.

BeiGene also partners with innovative companies who share our goal of developing therapies to address global health needs. We commercialize a range of oncology medicines in China licensed from Amgen, Bristol Myers Squibb, EUSA Pharma, and Bio-Thera. We also plan to address greater areas of unmet need globally through our other collaborations including with Mirati Therapeutics, Seagen, and Zymeworks.

In January 2021, BeiGene and Novartis announced a collaboration granting Novartis rights to co-develop, manufacture, and commercialize BeiGene's anti-PD1 antibody tislelizumab in North America, Europe, and Japan. Building upon this productive collaboration, including a biologics license application (BLA) under U.S. Food and Drug Administration (FDA) review, BeiGene and Novartis announced an option, collaboration, and license agreement in December 2021 for BeiGene's TIGIT inhibitor ociperlimab that is in Phase 3 development. Novartis and BeiGene also entered into a strategic commercial agreement through which BeiGene is promoting five approved Novartis Oncology products across designated regions of China.

About BeiGene

BeiGene is a global, science-driven biotechnology company focused on developing innovative and affordable medicines to improve treatment outcomes and access for patients worldwide. With a broad portfolio of more than 40 clinical candidates, we are expediting development of our diverse pipeline of novel therapeutics through our own capabilities and collaborations. We are committed to radically improving access to medicines for two billion more people by 2030. BeiGene has a growing global team of over 8,000 colleagues across five continents. To learn more about BeiGene, please visit www.beigene.com and follow us on Twitter at @BeiGeneGlobal.

IMPORTANT U.S. 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 hemorrhage 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, developed 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 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 1 week after the last dose. Advise men to avoid fathering a child during treatment and for 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, 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%), 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 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.

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

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 advancement, anticipated clinical development, regulatory milestones and commercialization of tislelizumab and zanubrutinib and BeiGene's plans, commitments, aspirations and goals under the headings "BeiGene Oncology" and "About BeiGene." 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 medicines and drug candidates, if approved; BeiGene's ability to obtain and maintain protection of intellectual property for its medicines and technology; BeiGene's reliance on third parties to conduct drug development, manufacturing and other services; BeiGene's limited experience in obtaining regulatory approvals and commercializing pharmaceutical products and its ability to obtain additional funding for operations and to complete the development of its drug candidates and achieve and maintain profitability; and the impact of the COVID-19 pandemic on BeiGene's clinical development, regulatory, commercial, manufacturing, and other operations, 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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