BeiGene Announces Clinical Results from Three Posters on Zanubrutinib Presented at the 24th Congress of European Hematology Association (EHA)

First Preliminary Data from Exploratory MYD88^{WT} Patient Cohort in Phase 3 Trial in Waldenström's Macroglobulinemia (WM)*; Updated Phase 1/2 WM Data; and Pooled Safety Data Analysis on Zanubrutinib in B-Cell Malignancies Presented*

Company to Host Investor Conference Call and Webcast of Mid-2019 Clinical Data Updates on Thursday, June 20, 2019 at 8:00 a.m. EDT

CAMBRIDGE, Mass. and BEIJING, China, June 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 the first presentation of clinical results from the ASPEN trial, a global randomized Phase 3 open-label trial of its investigational BTK inhibitor zanubrutinib in patients with Waldenström's Macroglobulinemia (WM). The poster presentation included clinical results from a nonrandomized exploratory cohort of patients with the MYD88^{WT} genotype of WM. In addition, BeiGene announced updated results from the ongoing Phase 1/2 trial of patients with WM; and a pooled safety data analysis of zanubrutinib from six ongoing monotherapy studies in patients with B-cell malignancies. These data were presented in three posters at the 24th European Hematology Association (EHA) Congress, taking place June 13-16 in Amsterdam.

"We are excited to announce new data from ongoing zanubrutinib clinical studies at EHA, including the first results of the Phase 3 ASPEN trial from a non-randomized cohort of patients who have WM with the MYD88^{WT} genotype. For these patients, who typically have poorer prognoses with lower response rates, we recognize the real need for a highly potent and selective BTK inhibitor that can sustain BTK inhibition and reduce off-target effects. We are excited that these data have echoed what we saw in earlier trials, with an overall response rate of 81 percent and a major response rate that includes patients with a partial response or better, of 54% including 23% with a very good partial response (VGPR)," said Jane Huang, M.D., Chief Medical Officer, Hematology, at BeiGene. "We will continue to follow these patients to further assess outcomes. Full results from the trial are planned for presentation at a medical congress later this year."

Dr. Huang continued, "In addition, with longer follow-up from the global Phase 1/2 trial of zanubrutinib in patients with WM, we're seeing high rates of CR/VGPR (42%) that are proving to be durable responses. Separately, the pooled safety data analysis of

zanubrutinib continues to affirm its tolerability as a selective BTK inhibitor, in patients with B-cell malignancies. We believe that these data further support zanubrutinib's potential to become a meaningful treatment option for patients with B-cell malignancies around the world."

Major Responses in Patients with MYD88 Wildtype WM Treated with Zanubrutinib

Abstract Number: PF487

The ASPEN trial, a randomized open-label, multicenter Phase 3 trial (clinicaltrials.gov Identifier: NCT03053440) of zanubrutinib vs. ibrutinib in patients with WM, has enrolled 26 patients who were centrally determined at study entry to have the $MYD88^{WT}$ genotype. These patients were enrolled in the non-randomized cohort and assigned to receive zanubrutinib 160mg twice daily (BID). Responses were assessed using modified IWWM-6 criteria with endpoints of combined rate of complete response (CR) and very good partial response (VGPR), overall response rate (ORR), major response rate (MRR) and safety.

This exploratory analysis included five patients with treatment-naïve (TN) disease and 21 patients with relapsed/refractory (R/R) WM.

As of February 28, 2019, the median follow-up was 12.2 months (range 2.3 – 21.7 months) and 17 patients remained on study. Results included:

- The ORR was 80.8%. MRR (partial response or better) was 53.8% and the VGPR rate was 23.1%. One patient achieved a complete response by IgM criteria with normal IgM levels and negative immunofixation;
- Median time to first major response (partial response or better) was 2.9 months;
- Median progression-free survival (PFS) and overall survival (OS) have not yet been reached;
- Zanubrutinib tolerability was generally consistent with previous reports. Discontinuation due to adverse events (AEs) occurred in 7.7% of patients (n=2). The primary reason for discontinuation was progressive disease;
- The most common AEs (in >15% pts) were diarrhea (19%), hypertension (19%), contusion (15%), constipation (15%), muscle spasm (15%), pneumonia (15%), and upper respiratory tract infection (15%);
- There were no fatal AEs or atrial fibrillation/flutter events reported; and

- Among adverse events of special interest for BTK inhibitors, bleeding was observed in nine patients (34.6%), hypertension was observed in five patients (19.2%), Grade 3 or 4 cytopenias were observed in four patients (15.4%), Grade 3 or 4 infections were observed in three patients (11.5%), and secondary malignancy in three patients (11.5%). Two patients had major hemorrhage (7.7%).

“Zanubrutinib is a highly potent and selective BTK inhibitor with good bioavailability that was generally well-tolerated in this exploratory cohort from the Phase 3 ASPEN trial, said Meletios A. Dimopoulos, M.D., Professor of Hematology and Medical Oncology, Chairman of the Department of Clinical Therapeutics, Rector of the National and Kapodistrian University of Athens, Greece and first author on the poster. “For the patients with wildtype MYD88 genotype, we are excited by these data that support the results we’ve seen previously from Phase 1/2 studies.”

Summary of Updated Clinical Results From the Global Phase 1/2 Trial

Abstract Number PF481

This global, open-label Phase 1/2 trial (clinicaltrials.gov identifier: NCT02343120) of zanubrutinib as monotherapy in patients with B-cell malignancies, including a cohort of patients with WM, is being conducted in Australia, New Zealand, the United States, Italy, the United Kingdom and South Korea. As of September 16, 2018, 77 patients with TN (n=24) or R/R (n=53) WM without prior BTK exposure have been enrolled in the trial; the median follow-up time was 23.9 months (4.4-45.7). Seventy-three patients including 24 with TN and 49 with R/R WM, were evaluable for efficacy in this analysis, per modified IWWM-6 criteria. At the time of the data cutoff, 61 patients remained on study treatment. Updated results included:

- The ORR by independent review committee (IRC) was 92% (67/73) including MRR of 82% (60/73) and CR / VGPR rate of 42% (31/73).
- The estimated PFS rate at 12 and 24 months was 90% and 81%, respectively;
- Zanubrutinib tolerability was generally consistent with previous reports in patients with various B-cell malignancies and AEs were predominantly grade 1 or 2 in severity. The most frequent AEs were upper respiratory tract infection (46%), contusion (30%), cough (20%), headache (18%) and diarrhea (17%);

- Grade 3-4 AEs occurred in 51.9% of patients. Grade 3-4 AEs of any attribution reported in > 3 patients included neutropenia (10%); anemia (7.8%), basal cell carcinoma (5%) and hypertension (5%); and
- With a median follow up 24 months, discontinuation due to AEs occurred in 10.4% of patients, with five fatal events.

“As we continue to follow the Phase 1/2 trial of zanubrutinib, now for more than four years, we are impressed by the tolerability and efficacy of this BTK inhibitor for patients with WM who had not received prior BTK inhibition therapy,” said Judith Trotman, MBChB, FRACP, FRCPA, Clinical Professor at Concord Repatriation General Hospital, Concord, New South Wales, Australia and first author on the poster.

Pooled Analysis of Satefy Data from Monotherapy Studies of Zanubrutinib in B-cell Malignancies

Abstract Number PS1159

Safety results from six ongoing, Phase 1 and Phase 2 clinical trials of zanubrutinib monotherapy, including collectively 682 patients with non-Hodgkin’s lymphoma (NHL), WM, or chronic lymphocytic leukemia/small lymphocytic lymphoma (CLL/SLL), were included in this comprehensive analysis. The majority of patients had R/R disease; almost all patients received zanubrutinib at a dose of 320mg once daily or 160mg twice daily. The median duration of zanubrutinib exposure was 13.4 months (0.1-49.7).

This analysis included an evaluation of the frequency and severity of AEs, AEs of Special Interst (AESIs), and AEs leading to death, dose reduction or treatment discontinuation (d/c).

Ninty-seven percent of patients reported at least one AE, which were primarily grade 1 or 2. The most common AEs of all grades included upper respiratory tract infection (32.4%), neutrophil count decreased (25.2%), diarrhea (19.4%), cough (19.1%), contusion (18.6%), and rash (18%). The most common grade ≥3 AEs included neutrophil count decreased (14.4%), anemia (7.6%), neutropenia (6.6%), pneumonia (4.5%), platelet count decreased (4.3%), and lung infection (4.1%). Serious AEs (SAEs) consisting primarily of infectious complications such as pneumonia/lung infection were reported in 36% of patients.

AESIs such as atrial fibrillation/flutter (1.9%), major hemorrhage (2.5%), and grade ≥3 hypertension (3.4%) were infrequent, and treatment discontinuation due to AEs was uncommon (9.1% overall, including 3.5% for whom the event(s) were treatment-

related).

“Zanubrutinib was generally well-tolerated, with less than five percent discontinuation for treatment-related adverse events. These data also demonstrated low safety-related treatment failure rates at doses of zanubrutinib associated with complete and sustained BTK inhibition,” commented Constantine S. Tam, M.D., Disease Group Lead for Low Grade Lymphoma and Chronic Lymphocytic Leukemia at Peter MacCallum Cancer Center and Director of Hematology at St. Vincent’s Hospital, Australia, and lead author of the poster presentation.

Mid-2019 Clinical Data Update Conference Call and Webcast Information:

BeiGene will host a conference call and webcast on Thursday, June 20 at 8:00 a.m. EDT. Investors and analyst are invited to join the conference call using the following dial-in information:

U.S. Toll-Free: +1 (844) 461-9930
U.S. Toll: +1 (478) 219-0535
Hong Kong Toll-Free: +852 800 279 19250
China Toll-Free: +86 800 914 686
Conference ID: 1790069

A live webcast of the conference call can be accessed from the investors section of BeiGene’s website at http://ir.beigene.com/ or http://hkexir.beigene.com. An archived replay will be available two hours after the event for 90 days.

About Zanubrutinib

Zanubrutinib (BGB-3111) is an investigational small molecule inhibitor of Bruton’s tyrosine kinase (BTK) discovered by BeiGene scientists that is currently being evaluated in a broad pivotal clinical program globally as a monotherapy and in combination with other therapies to treat various B-cell malignancies.

Clinical trials of zanubrutinib include a fully-enrolled, global Phase 3 clinical trial in patients with Waldenström macroglobulinemia (WM) comparing zanubrutinib to ibrutinib, currently the only approved BTK inhibitor for WM; a global Phase 3 clinical trial in patients with previously untreated chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL); a pivotal Phase 2 trial in patients with relapsed/refractory (R/R) follicular lymphoma in combination with GAZYVA® (obinutuzumab); a Phase 3 trial comparing zanubrutinib to ibrutinib in patients with R/R CLL/SLL; and a global Phase 1 trial. In China, BeiGene has completed two pivotal Phase 2 clinical trials of

zanubrutinib in patients with MCL and CLL/SLL and the enrollment in the pivotal Phase 2 clinical trials in patients with WM.

Zanubrutinib has been granted by the U.S. Food and Drug Administration (FDA) Fast Track designation for the treatment of patients with WM, and Breakthrough Therapy designation for the treatment of adult patients with MCL who have received at least one prior therapy. The New Drug Applications (NDAs) in China for R/R MCL and R/R CLL/SLL have been accepted by the China National Medical Products Administration (NMPA) and granted priority review. BeiGene plans to submit its first NDA in the U.S. for zanubrutinib in 2019 or early 2020.

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 approximately 2,400 employees in China, the United States, 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. BeiGene markets ABRAXANE® (nanoparticle albumin–bound paclitaxel), REVLIMID® (lenalidomide), and VIDAZA® (azacitidine) in China under a license from Celgene Corporation.[1]

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 the encouraging clinical data from clinical trials of zanubrutinib and BeiGene’s advancement of, and anticipated clinical development, regulatory milestones and commercialization of zanubrutinib. 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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