
BeiGene Presents Pivotal Phase 2 Clinical Results of Zanubrutinib in Patients with Relapsed/Refractory Chronic Lymphocytic Leukemia or Small Lymphocytic Lymphoma at the 15th International Conference on Malignant Lymphoma (ICML)

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

CAMBRIDGE, Mass. and BEIJING, China, June 20, 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 results from an ongoing pivotal Phase 2 clinical study of its investigational BTK inhibitor zanubrutinib being conducted in China in patients with relapsed/refractory (R/R) chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) in an oral presentation at the 15th International Conference on Malignant Lymphoma (ICML), taking place June 18-22, 2019 in Lugano, Switzerland.

“The results of this trial in patients with relapsed/refractory CLL or SLL are part of our NDA in China, where patients with this disease have far fewer treatment options than in the West. At BeiGene, we are committed to improving treatment outcomes and access for patients worldwide,” said Jane Huang, M.D., Chief Medical Officer, Hematology, at BeiGene.

Summary of Updated Clinical Results from the Pivotal Phase 2 Study Being Conducted in China

This single-arm, pivotal Phase 2 trial (clinicaltrials.gov identifier: NCT03206918) of zanubrutinib as a monotherapy in patients with R/R CLL/SLL is the basis for BeiGene’s new drug application (NDA) for this indication which is currently under review by the China National Medical Products Administration (NMPA). The trial is being conducted in China, and enrolled 91 patients from 11 study centers, including 82 patients with CLL and nine with SLL. Patients were treated with zanubrutinib, dosed at 160 mg orally twice-daily (BID). The primary endpoint of the trial was overall response rate (ORR) assessed by independent review committee (IRC) using iwCLL 2008 criteria for CLL and CT-based assessment according to the Lugano Classification 2014 for SLL.

As of the December 14, 2018 data cutoff, 75 patients (82.4%) remained on study treatment. The median follow-up time for patients enrolled in the trial was 15.1 months (0.8-21.2). Results included:



- The ORR by IRC was 84.6% (77/91); the complete response (CR) rate was 3.3% (3/91); the partial response (PR) rate was 59.3% (54/91) and the PR with lymphocytosis (PR-L) was 22.0% (20/91). ORRs per IRC were generally consistent across different subgroups;
- The 12-month progression-free survival (PFS) was estimated at 87.2% and the median PFS had not been reached with median PFS follow-up at 12.9 months (0.8-20.4);
- Zanubrutinib tolerability was generally consistent with previous reports of zanubrutinib treatment in patients with various B-cell malignancies. The majority of treatment-emergent adverse events (TEAEs) were grade 1 or 2 in severity, with the most frequently reported TEAEs being neutrophil count decrease (68.1%), upper respiratory tract infection (45.1%), purpura (34.1%), and platelet count decreased (33.0%);
- Grade ≥ 3 TEAEs were reported in 75.8% of patients, with the most frequently reported being neutrophil count decrease (44.0%), lung infection (9.9%), upper respiratory tract infection (9.9%), platelet count decrease (8.8%), and anemia (8.8%); and
- Three patients had TEAEs leading to death (one case each of lung infection/cardiac failure/respiratory, cardiopulmonary failure, and multiple organ dysfunction syndrome in the setting of disease progression); these were determined unlikely or unrelated to zanubrutinib treatment.

“With trial enrollment completed in 2017, we are continuing to follow its participants to assess zanubrutinib’s activity for patients with R/R CLL or SLL. We are pleased that these data demonstrated 85% ORR by IRC and that the tolerability has been consistent with previous reports,” said Wei Xu, M.D., Ph.D., Deputy director of the hematology department at The First Affiliated Hospital of Nanjing Medical University in China, and the presenting author of the trial.

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

BeiGene will host a conference call and webcast today, Thursday, June 20 at 8:00 a.m. EDT. Investors and analysts 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 Chronic Lymphocytic Leukemia and Small Lymphocytic Lymphoma

Chronic lymphocytic leukemia (CLL) and small lymphocytic lymphoma (SLL) are forms of non-Hodgkin lymphoma, a type of blood cancer, that arise from B lymphocytes. CLL and SLL are essentially the same disease, with the only difference being the location where the cancer primarily occurs.¹ When most of the cancer cells are located in the peripheral blood and the bone marrow, the disease is referred to as CLL, although the lymph nodes and spleen are often involved. When the cancer cells are located mostly in the lymph nodes, the disease is called SLL.²

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 R/R MCL and R/R 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 over 2,500 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.³

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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¹ "Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma" Fact Sheet, Lymphoma Research Foundation. Accessed at: https://www.lymphoma.org/wp-content/uploads/2018/04/LRF_FACTSHEET_CLL_SLL.pdf

² Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma," Lymphoma Research Foundation. Accessed at: <https://www.lymphoma.org/aboutlymphoma/cll/>

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