
BeiGene Initiates Global Phase 2 Trial of Zanubrutinib in Patients with Relapsed or Refractory Marginal Zone Lymphoma

CAMBRIDGE, Mass. and BEIJING, China, February 19, 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 the first patient was dosed in a global Phase 2 trial of zanubrutinib, an investigational inhibitor of Bruton's tyrosine kinase (BTK), in patients with relapsed or refractory (R/R) marginal zone lymphoma (MZL), which BeiGene refers to as the MAGNOLIA trial.

Zanubrutinib was discovered by BeiGene scientists and is being developed globally as a monotherapy and in combination with other therapies to treat various hematologic malignancies. Zanubrutinib is being studied in several clinical trials as part of a broad development program and was granted Breakthrough Therapy designation for the treatment of adult patients with mantle cell lymphoma (MCL) who have received at least one prior therapy, and Fast Track designation for the treatment of patients with Waldenström macroglobulinemia (WM) by the U.S. Food and Drug Administration (FDA). BeiGene plans to submit an initial new drug application (NDA) to the FDA for zanubrutinib in 2019 or early 2020. In addition, BeiGene has submitted NDAs in China for R/R MCL and R/R chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL), which have been accepted for review by the National Medical Products Administration (NMPA) and granted priority review.

"We are excited to initiate this Phase 2 trial following the preliminary results from our Phase 1 trial of zanubrutinib in patients with relapsed or refractory marginal zone lymphoma, in which seven objective responses in nine patients were reported. More than 1,300 patients worldwide have been treated with zanubrutinib, and we look forward to evaluating its potential in the MAGNOLIA trial for these patients who may find benefit with this novel BTK inhibitor," commented Jane Huang, M.D., Chief Medical Officer for Hematology at BeiGene.

The global, Phase 2, open-label, multi-center MAGNOLIA trial is expected to enroll approximately 65 patients with R/R MZL. The primary efficacy endpoint is overall response rate (ORR) determined by independent central review. Key secondary endpoints include progression-free survival (PFS), overall survival (OS), duration of response (DoR), ORR by investigator assessment, and safety and tolerability.

For more information about the trial, patients and physicians should email BeiGene at clinicaltrials@beigene.com.

About Marginal Zone Lymphoma

Marginal zone lymphoma is a group of indolent (slow growing) B-cell lymphomas that account for approximately 8% of all non-Hodgkin's lymphoma (NHL) cases, according to the Lymphoma Research Foundation.¹ The average age at diagnosis is 60 years, and it is slightly more common in women than in men.¹ There are three types of MZL: extranodal marginal zone B-cell lymphoma or mucosa-associated lymphoid tissue (MALT), the most common type of MZL, which occurs outside the lymph nodes in places such as the stomach, small intestine, salivary gland, thyroid, eyes, and lungs; nodal marginal zone B-cell lymphoma, which occurs within the lymph nodes; and splenic marginal zone B-cell lymphoma, which occurs most often in the spleen and blood.

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 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.

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 1,700 employees in China, the United States, Australia and Switzerland, 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.²

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 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 <https://www.lymphoma.org/aboutlymphoma/nhl/mzl/>

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