

BeiGene Initiates Global Phase III Trial of the BTK Inhibitor BGB-3111 in Waldenström's Macroglobulinemia

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CAMBRIDGE, MA, USA | January 25, 2017 | BeiGene, Ltd. (BGNE) a clinical-stage biopharmaceutical company developing innovative molecularly-targeted and immuno-oncology drugs for the treatment of cancer, today announced the initiation of a global, randomized Phase III trial of its investigational Bruton's Tyrosine Kinase (BTK) inhibitor BGB-3111 in patients with Waldenström's macroglobulinemia (WM). The study is designed to determine whether the quality of response with BGB-3111 in WM is superior to that of ibrutinib, the currently approved BTK inhibitor. Approximately 170 patients are expected to be enrolled at clinical sites in North America, Europe, Australia, and New Zealand.

"The recently presented data from the Phase I study of BGB-3111 in B-cell malignancies demonstrated a high response rate in patients with WM, including a very good partial response rate of 34%. In addition, no cases of disease progression have been observed, and only one patient out of the 45 enrolled at the time of the data cutoff discontinued treatment for any reason. These data, reflective of BGB-3111's demonstrated ability to produce complete and continuous BTK inhibition in both blood and lymph nodes, are sufficiently encouraging to warrant a superiority comparison with ibrutinib, the current treatment standard for WM," commented Constantine Tam, MD, Disease Group Lead for Low Grade Lymphoma and Chronic Lymphocytic Leukemia at Peter MacCallum Cancer Centre and Director of Haematology at St. Vincent's Hospital, Australia, a member of the steering committee of the Phase III study.

"BGB-3111 is the first BTK inhibitor to be evaluated in a head-to-head Phase III trial designed to establish superiority over ibrutinib. In addition to WM, we will continue to develop BGB-3111 broadly in B-cell malignancies and also look forward to initiating pivotal studies for BGB-3111 in China in the first half of 2017," commented Jane Huang, M.D., Chief Medical Officer for Hematology at BeiGene.

"We are excited to announce the initiation of the first global, pivotal clinical trial of one of our four internally-developed assets, which marks an important milestone for our company. This trial is the first of a number of pivotal trials we plan to initiate, both globally and in China, for our assets in 2017," commented John V. Oyler, Founder, Chief Executive Officer, and Chairman of BeiGene.

Trial Design

This Phase III trial is designed to determine whether BGB-3111 is superior to ibrutinib based upon the combined rate of complete responses (CRs) and very good partial responses (VGPRs), response levels which are correlated with improved outcomes in WM patients who require therapy. The study will enroll relapsed / refractory or treatment-naïve WM patients who are inappropriate for chemo-immunotherapy. At the time of enrollment, patients will be tested for mutation status of the *MYD88* gene and assigned accordingly to one of two trial cohorts. The first cohort will enroll approximately 150 patients with MYD88 mutations, which are characteristic of WM and present in >90% of cases. These patients will be randomized in a 1:1 ratio to receive either BGB-3111 160 mg orally twice daily (BID) or ibrutinib 420 mg once daily (QD) until progression. The trial's primary endpoint is combined rate of CRs and VGPRs. A key secondary endpoint is major response rate (MRR, defined as partial response or better), which will be hierarchically tested for non-inferiority followed by superiority. Other secondary endpoints will include progression-free survival, duration of response, and symptom resolution. The randomization will be stratified by CXCR4 mutational status and number of lines of prior therapy.

Patients with MYD88 wildtype status will be enrolled in a second cohort and will receive BGB-3111 160 mg BID until progression. Patients will be assessed for the combined rate of CRs and VGPRs, MRR, and safety.

About BGB-3111

BGB-3111 is a potent and highly selective investigational small molecule inhibitor of BTK. BGB-3111 has demonstrated higher selectivity against BTK than ibrutinib (the only BTK inhibitor currently approved by the U.S. Food and Drug Administration and the European Medicines Agency) based on biochemical assays, higher exposure in patients than ibrutinib based on their respective Phase I experiences, and complete and sustained 24-hour BTK occupancy in both the blood and the lymph node.

About BeiGene

BeiGene is a global, clinical-stage, research-based biotechnology company focused on molecularly targeted and immuno-oncology cancer therapeutics. With a team of over 300 scientists, clinicians and staff in mainland China, the United States, Australia and Taiwan, BeiGene is advancing a pipeline consisting of novel oral small molecules and monoclonal antibodies for cancer. BeiGene is working to create combination solutions aimed to have both a meaningful and lasting impact on cancer patients.

SOURCE: BeiGene

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