

BeiGene Regains Full Global Rights to Its Investigational Anti-PD-1 Antibody Tislelizumab

CAMBRIDGE, Mass. and BEIJING, China; June 17, 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 it has entered into a mutual agreement with Celgene Corporation to terminate the parties' global collaboration for tislelizumab, BeiGene's investigational anti-PD-1 antibody, in advance of the pending acquisition of Celgene by Bristol-Myers Squibb. In connection with the termination, Celgene has agreed to pay \$150 million to BeiGene.

"Our collaboration with Celgene was instrumental for the late-stage clinical development of tislelizumab and has provided us with significant resources to continue our broad clinical program," said John V. Oyler, Co-Founder, Chief Executive Officer, and Chairman of BeiGene. "As we have been leading most of the ongoing Phase 3 or potentially registration-enabling trials with a global development organization of over 800 people, we believe that we are well-positioned to continue the development of tislelizumab. I am proud of the work that we have accomplished in collaboration with Celgene and am excited by the tremendous opportunity that we have ahead now that we've regained full global rights to tislelizumab."

Tislelizumab has been dosed in over 2,950 patients globally. With two new drug applications under review in China, BeiGene expects tislelizumab to receive its first regulatory approval later this year.

In July 2017, BeiGene and Celgene announced a global strategic collaboration in which Celgene obtained exclusive rights to develop and commercialize tislelizumab in solid tumor cancers in the United States, Europe, Japan and the rest of world outside of Asia. BeiGene retained rights in hematology indications globally and in solid tumor cancers in Asia (ex-Japan). In connection with that agreement, BeiGene also acquired Celgene's commercial operations in China and an exclusive license to Celgene's cancer commercial portfolio in China (ABRAXANE[®], REVLIMID[®], VIDAZA[®]). BeiGene's commercial license from Celgene is not affected by the termination of the tislelizumab agreement. In the almost two years since the transaction, BeiGene has grown its commercial organization in China to more than 600 people.

About Tislelizumab

Tislelizumab (BGB-A317) is an investigational humanized IgG4 anti-PD-1 monoclonal antibody 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 candidate produced from BeiGene's immuno-oncology biologic program, and is being developed as a monotherapy and in combination with other therapies for the treatment of a broad array of both solid tumor and hematologic cancers.

Tislelizumab is being studied in a broad clinical program. BeiGene has completed a pivotal Phase 2 clinical trial in patients with relapsed or refractory (R/R) classical Hodgkin's lymphoma (cHL). Ongoing clinical trials of tislelizumab include a Phase 3 clinical trial in patients with second-line or third-line non-small cell lung cancer (NSCLC); a Phase 3 clinical trial in first-line patients with hepatocellular carcinoma (HCC); a Phase 3 clinical trial in second-line patients with esophageal squamous carcinoma (ESCC); a Phase 3 clinical trial in first-line patients with gastric cancer (GC); a Phase 3 clinical trial in first-line patients with ESCC; a Phase 2 clinical trial in second- or third-line patients with HCC; and a Phase 1 clinical trial in patients with R/R NK/T-cell lymphomas. The aforementioned studies are enrolling patients in multiple countries, including the U.S., Europe, and China.

Additionally, BeiGene is conducting a Phase 3 clinical trial in first-line patients with non-squamous NSCLC; a Phase 3 clinical trial in first-line patients with squamous NSCLC; a Phase 3 clinical trial in patients with nasopharyngeal cancer (NPC); a Phase 3 clinical trial in first-line patients with urothelial carcinoma (UC); a pivotal Phase 2 clinical trial in patients with locally advanced or metastatic urothelial cancer; and a pivotal Phase 2 trial in patients with MSI-H or dMMR solid tumors. These studies are enrolling patients in China.

New drug applications (NDA) for tislelizumab in patients with R/R cHL and in patients with locally advanced or metastatic UC have been accepted by the China National Medical Products Administration (NMPA, formerly known as CFDA) and the R/R cHL filing has been 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 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.ⁱ

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 tislelizumab and its commercialization in China of ABRAXANE®, REVLIMID®, VIDAZA®. 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.

Investor Contact

Craig West
+1 857-302-5189
ir@beigene.com

Media Contact

Liza Heapes
+ 1 857-302-5663
media@beigene.com

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