Priority Review Granted to BeiGene’s New Drug Application of Pamiparib in Ovarian Cancer in China

BEIJING, China and CAMBRIDGE, Mass., July 27, 2020 (GLOBE NEWSWIRE) -- BeiGene, Ltd. (NASDAQ: BGNE; HKEX: 06160), a commercial-stage biotechnology company, today announced that the Center for Drug Evaluation (CDE) of the China National Medical Products Administration (NMPA) has granted priority review status to the New Drug Application (NDA) of pamiparib, BeiGene’s investigational inhibitor of PARP1 and PARP2, for the treatment of patients with deleterious or suspected deleterious germline BRCA-mutated advanced ovarian, fallopian tube, or primary peritoneal cancer who have been treated with two or more lines of chemotherapy.

“Pamiparib is our third internally developed drug candidate that has been granted priority review in China, following tislelizumab and BRUKINSA. It received priority review within a week of the acceptance of the application, reflecting the unmet need for patients with this advanced disease,” commented Yong (Ben) Ben, M.D., Chief Medical Officer, Immuno-Oncology at BeiGene. “We look forward to presenting the clinical data that support this NDA at an upcoming medical conference and the next milestones in the pamiparib program.”

The NDA of pamiparib as a potential treatment for patients with advanced ovarian, fallopian tube, or primary peritoneal cancer was accepted in July 2020. It is supported by clinical results from the pivotal Phase 2 portion of the Phase 1/2 trial (NCT03333915), which enrolled 113 patients in China with high-grade epithelial ovarian cancer (including fallopian tube or primary peritoneal cancer) or high-grade endometrioid epithelial cancer, harboring germline BRCA1/2 mutation, following at least two prior lines of standard chemotherapy. BeiGene is developing pamiparib as a monotherapy and in combination with other therapies for the treatment of a broad array of solid tumors.

Priority review and approval was established in China to facilitate drug registration management and accelerate the development of innovative drugs with significant clinical advantages and for which there is an urgent clinical need. According to the Drug Registration Regulation (Bureau Order 27) implemented on July 1, 2020, the regulatory authority will prioritize the review process and evaluation resources for applications under priority review. These applications are expected to have reduced review and approval timelines.

About Ovarian Cancer

In China, ovarian cancer is the tenth most common form of cancer among women, with over 50,000 new cases and more than 30,000 deaths in 2018. More than 60 percent of patients are diagnosed with advanced disease. The standard therapy for ovarian cancer consists of surgery followed by postoperative platinum-based chemotherapy. An estimated 70 percent of patients with epithelial ovarian cancer, which accounts for more than 90 percent of all ovarian cancer, who achieve a full remission following first-line therapy will develop recurrent disease.
About Pamiparib

Pamiparib (BGB-290) is an investigational inhibitor of PARP1 and PARP2 which has demonstrated pharmacological properties such as brain penetration and PARP-DNA complex trapping in preclinical models. Discovered by BeiGene scientists, pamiparib is currently in global clinical development as a monotherapy or in combination with other agents for a variety of solid tumor malignancies. To date, more than 1,200 patients have been enrolled in clinical trials of pamiparib.

A New Drug Applications (NDA) for pamiparib for patients with ovarian cancer has been accepted and granted priority review by the Center for Drug Evaluation (CDE) of the NMPA.

About the Pamiparib Clinical Program

Clinical trials of pamiparib include:

- Phase 3 trial in China of pamiparib as maintenance versus placebo in patients with platinum-sensitive recurrent ovarian cancer (NCT03519230);
- Phase 2 trial of pamiparib in patients with metastatic castration-resistant prostate cancer with homologous recombination deficiency (NCT03712930);
- Phase 2 trial in China of pamiparib in patients with metastatic HER2-negative breast cancer with BRCA mutation (NCT03575065);
- Phase 2 trial of pamiparib in patients with advanced or inoperable gastric cancer (NCT03427814);
- Phase 1/2 trial in China of pamiparib in patients with advanced ovarian cancer, fallopian cancer, and primary peritoneal cancer or advanced triple negative breast cancer (NCT03333915);
- Phase 1b/2 trial of pamiparib in combination with radiation therapy and/or temozolomide in patients with first-line or recurrent/refractory glioblastoma (NCT03150862);
- Phase 1b trial of pamiparib in combination with temozolomide in patients with locally advanced or metastatic solid tumors (NCT03150810); and
- Phase 1b trial of pamiparib in combination with tislelizumab for a variety of solid tumor malignancies (NCT02660034).

About BeiGene

BeiGene is a global, commercial-stage biotechnology company focused on discovering, developing, manufacturing, and commercializing innovative medicines to improve treatment outcomes and access for patients worldwide. Our 4,100+ employees in China, the United States, Australia, and Europe are committed to expediting the development of a diverse pipeline
of novel therapeutics for cancer. We currently market two internally-discovered oncology products: BTK inhibitor BRUKINSA® (zanubrutinib) in the United States and China, and anti-PD-1 antibody tislelizumab in China. We also market or plan to market in China additional oncology products licensed from Amgen Inc., Celgene Logistics Sàrl, a Bristol Myers Squibb (BMS) company, and EUSA Pharma. To learn more about BeiGene, please visit www.beigene.com and follow us on Twitter at @BeiGeneUSA.

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 further advancement of, and anticipated clinical development, regulatory milestones and commercialization of pamiparib; the expected reduced regulatory review and approval timelines in China for drugs with priority review status; the potential for pamiparib to offer a new treatment option for patients with ovarian cancer; and the release of data from clinical trials of pamiparib. 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 Globocan 2018; Bray et al 2018

2 Torre et al 2018

3 Mutch and Part 2014

4 McMeekin et al 2004