BeiGene, Ltd.
百濟神州有限公司
(incorporated in the Cayman Islands with limited liability)
(Stock Code: 06160)

INSIDE INFORMATION
CHINA NMPA APPROVES PARP INHIBITOR PAMIPARIB FOR PATIENTS WITH PREVIOUSLY TREATED ADVANCED OVARIAN CANCER

This announcement is issued pursuant to Rule 13.09 of the Rules Governing the Listing of the Securities on The Stock Exchange of Hong Kong Limited and under Part XIVA of the Securities and Futures Ordinance (Cap. 571).

On May 7, 2021, BeiGene, Ltd. ("**BeiGene**" or the "**Company**") announced that the Company's PARP inhibitor pamiparib has received conditional approval from the China National Medical Products Administration (NMPA) for the treatment of patients with germline BRCA (gBRCA) mutation-associated recurrent advanced ovarian, fallopian tube, or primary peritoneal cancer who have been treated with two or more lines of chemotherapy. The new drug application was previously granted priority review by the Center for Drug Evaluation (CDE) in July 2020. BeiGene is preparing to launch pamiparib this month.

Attached hereto as Schedule 1 is the full text of the press release issued by the Company on May 7, 2021 announcing the above-described business updates.

Cautionary Statement required by Rule 18A.08(3) of the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited: BeiGene may not be able to ultimately develop and market pamiparib successfully.

Forward-Looking Statements

This announcement contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 and other federal securities laws, including statements regarding data from the pivotal Phase 2 portion of the Phase 1/2 trial of pamiparib in patients with advanced solid tumors, the potential for pamiparib to provide clinical benefit to patients, BeiGene's advancement, anticipated clinical development, regulatory milestones and commercialization of pamiparib, and BeiGene's plans, commitments, aspirations and goals under the headings "BeiGene Oncology" and "About BeiGene". 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 medicines and drug candidates, if approved; BeiGene's ability to obtain and maintain protection of intellectual property for its medicines and technology; BeiGene's reliance on third parties to conduct drug development, manufacturing and other services; BeiGene's limited experience in obtaining regulatory approvals and commercializing pharmaceutical products and its ability to obtain additional funding for operations and to complete the development of its drug candidates and achieve and maintain profitability; and the impact of the COVID-19 pandemic on BeiGene's clinical development, regulatory, commercial and other operations, 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 and The Stock Exchange of Hong Kong Limited. All information in this announcement is as of the date of this announcement, and BeiGene undertakes no duty to update such information unless required by law.

The Company's shareholders and potential investors are advised not to place undue reliance on this announcement and to exercise caution in dealing in securities in the Company.

By order of the Board
BeiGene, Ltd.
Mr. John V. Oyler
Chairman

Hong Kong, May 7, 2021

As of the date of this announcement, the Board of Directors of the Company comprises Mr. John V. Oyler as Chairman and Executive Director, Dr. Xiaodong Wang and Mr. Anthony C. Hooper as Non-executive Directors, and Mr. Timothy Chen, Mr. Donald W. Glazer, Mr. Michael Goller, Mr. Ranjeev Krishana, Mr. Thomas Malley, Dr. Corazon (Corsee) D. Sanders, Mr. Jing-Shyh (Sam) Su and Mr. Qingqing Yi as Independent Non-executive Directors.

SCHEDULE 1

China NMPA Approves PARP Inhibitor Pamiparib for Patients with Previously Treated Advanced Ovarian Cancer

Pamiparib becomes the first PARP inhibitor approved in both platinum-sensitive and platinum-resistant relapsed ovarian cancer in China

This marks the first approval of pamiparib and the third BeiGene-discovered medicine to receive regulatory approval

BEIJING, China and CAMBRIDGE, Mass., May 7, 2021 — BeiGene, Ltd. (NASDAQ: BGNE; HKEX: 06160), a global biotechnology company focused on developing and commercializing innovative medicines worldwide, today announced that its PARP inhibitor pamiparib has received conditional approval from the China National Medical Products Administration (NMPA) for the treatment of patients with germline BRCA (gBRCA) mutation-associated recurrent advanced ovarian, fallopian tube, or primary peritoneal cancer who have been treated with two or more lines of chemotherapy. The new drug application was previously granted priority review by the Center for Drug Evaluation (CDE) in July 2020. BeiGene is preparing to launch pamiparib this month.

"Today's NMPA approval makes pamiparib the third BeiGene internally discovered and developed medicine to receive marketing authorization, an incredible company milestone validating our scientific innovations," commented Xiaobin Wu, Ph.D., President, Chief Operating Officer, and General Manager of China at BeiGene. "With a broad commercial portfolio of seven medicines covering 15 indications across hematological malignancies and solid tumors in China, our science-based commercial team is well-positioned to serve patients in need. BeiGene will continue working to advance our broad, diverse pipeline and executing on our mission of expanding access to and improving affordability of impactful treatments for patients worldwide."

"We are thrilled that pamiparib is the first PARP inhibitor approved in China for patients with both platinum-sensitive and platinum-resistant relapsed ovarian cancer. Pamiparib was uniquely designed to reduce drug resistance and sustain anti-tumor response, and as reported at last year's ESMO, this selective PARP inhibitor demonstrated high response rates and was generally well tolerated among patients," said Yong (Ben) Ben, M.D., Chief Medical Officer, Immuno-Oncology at BeiGene. "We appreciate the patients and investigators who participated in this trial, and hope that pamiparib will become an important treatment option for patients in China with recurrent ovarian cancer. In addition, we are evaluating pamiparib in several other trials and indications, including as a maintenance therapy for patients with platinum-sensitive recurrent ovarian cancer in an ongoing Phase 3 trial."

"Disease recurrence is common among patients with advanced ovarian cancer and, due to the limited efficacy and unacceptable toxicity of chemotherapy, PARP inhibitors have become established treatment options in later lines of therapy. The encouraging pivotal Phase 2 data demonstrated that pamiparib can provide clinically meaningful and durable responses for patients who are sensitive or resistant to platinum-based chemotherapy. We believe that the approval of pamiparib will bring a new hope for these patients and their loved ones," commented Xiaohua Wu, M.D., Ph.D., Professor and Chair of Gynecologic Oncology Department at Fudan University Shanghai Cancer Center and lead investigator for the trial.

The NMPA conditional approval of pamiparib for the treatment of patients with advanced ovarian, fallopian tube, or primary peritoneal cancer is based on clinical results from a pivotal Phase 2 portion of the Phase 1/2 trial (NCT03333915). A total of 113 patients in China with high-grade, non-mucinous, epithelial ovarian cancer (including fallopian or primary peritoneal cancer), harboring *gBRCA* mutations, following at least two prior lines of standard chemotherapy, were enrolled in the pivotal Phase 2 portion of the trial, including 90 patients with advanced platinum-sensitive ovarian cancer (PSOC), and 23 patients with advanced platinum-resistant ovarian cancer (PROC).

Clinical efficacy data in the pamiparib label in China, as assessed by independent review committee (IRC) per RECIST v1.1, were based on 101 patients evaluable for efficacy analysis, including 82 patients with PSOC and 19 patients with PROC. For patients with PSOC, with a median follow-up time of 17.0 months, the objective response rate (ORR) was 68.3% (95% CI: 57.1, 78.1) and the median duration of response (DoR) was 13.8 months (95% CI: 10.97, 20.73); for patients with PROC, the median follow-up time was 11.6 months, the ORR was 31.6% (95% CI: 12.6, 56.6) and the median DoR was 11.1 months (95% CI: 4.21, 16.59).

The safety profile of pamiparib in the label in China was based on 317 patients who received pamiparib as a monotherapy in three clinical trials. The most common adverse reactions (≥10%) were anemia, nausea, leukopenia, neutropenia, vomiting, fatigue, thrombocytopenia, decreased appetite, diarrhea, abdominal pain, aspartate aminotransferase (AST) increased, alanine aminotransferase (ALT) increased, blood bilirubin increased, and lymphopenia. Grade ≥3 adverse reactions occurred in 55.8% of patients, with the most common (≥1%) being anemia, neutropenia, leukopenia, thrombocytopenia, lymphopenia, vomiting, fatigue, diarrhea, nausea, and AST increased. Serious adverse reactions occurred in 21.5% of patients, with the most common (≥1%) being anemia and leukopenia.

The most common adverse reactions reported from the pivotal Phase 2 trial in the label in China (≥10%) were anemia, leukopenia, nausea, neutropenia, vomiting, thrombocytopenia, decreased appetite, fatigue, abdominal pain, ALT increased, diarrhea, AST increased, lymphopenia, gamma-glutamyltransferase increased, upper respiratory tract infection, blood bilirubin increased, malaise, weight decreased, and dizziness. Grade ≥3 adverse reactions occurred in 71.7% of patients, with the most common (≥1%) being anemia, neutropenia, leukopenia, thrombocytopenia, lymphopenia, vomiting, diarrhea, gamma-glutamyltransferase increased, hypokalemia, abdominal pain, fatigue, upper respiratory tract infection, pancytopenia, and hypertension.

The recommended dose of pamiparib is 60 mg twice daily (BID) taken orally.

About Ovarian Cancer

Ovarian cancer is the seventh most common cancer among women, accounting for 295,525 cases in 2018.[i] More than 60 percent of patients are diagnosed with advanced disease and approximately 70 percent will develop recurrent disease due to chemotherapy resistance, resulting in a high mortality rate.[ii,iii] In China, ovarian cancer is the deadliest gynecologic cancer, responsible for approximately 22,500 deaths every year, and the five-year survival rate among Chinese patients is about 40%.[iv,v]

About Pamiparib

Pamiparib is an 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.

In China, pamiparib received conditional approval for treatment of patients with germline BRCA (gBRCA) mutation-associated recurrent advanced ovarian, fallopian tube, or primary peritoneal cancer who have been treated with two or more lines of chemotherapy in May 2021. Full approval for this indication is contingent upon results from ongoing corroborative trials confirming the clinical benefit of pamiparib in this population.

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).

BeiGene Oncology

BeiGene is committed to advancing best and first-in-class clinical candidates internally or with like-minded partners to develop impactful and affordable medicines to patients across the globe. We have a growing R&D team of approximately 2,300 colleagues dedicated to advancing more than 80 clinical trials involving more than 13,000 patients. Our expansive portfolio is directed by a predominantly internalized clinical development team supporting trials in more than 40 countries. Hematology-oncology and solid tumor targeted therapies and immuno-oncology are key focus areas for the Company, with both mono- and combination therapies prioritized in our research and development. The Company currently markets two medicines discovered and developed in our labs: BTK inhibitor BRUKINSA in the United States, China, Canada, and additional international markets, and non-FC-gamma receptor binding anti-PD-1 antibody tislelizumab in China.

BeiGene also partners with innovative companies who share our goal of developing therapies to address global health needs. We commercialize a range of oncology medicines in China licensed from Amgen and Bristol Myers Squibb. We also plan to address greater areas of unmet need globally through our collaborations including with Amgen, Bio-Thera, EUSA Pharma, Mirati Therapeutics, SeaGen, and Zymeworks. BeiGene has also entered into a collaboration with Novartis Pharma AG granting Novartis rights to develop, manufacture, and commercialize tislelizumab in North America, Europe, and Japan.

About BeiGene

BeiGene is a global, science-driven biotechnology company focused on developing innovative and affordable medicines to improve treatment outcomes and access for patients worldwide. With a broad portfolio of more than 40 clinical candidates, we are committed to expediting the development of our diverse pipeline of novel therapeutics through collaborations or our own internal capabilities, with the aspirational goal of radically improving access to medicines for two billion more people by 2030. BeiGene is a headquarter-less company by design, with a growing global team of approximately 6,000 colleagues across five continents. To learn more about BeiGene, please visit www.beigene.com and follow us on Twitter at @BeiGeneGlobal.

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 data from the pivotal Phase 2 portion of the Phase 1/2 trial of pamiparib in patients with advanced solid tumors, the potential for pamiparib to provide clinical benefit to patients, BeiGene's advancement, anticipated clinical development, regulatory milestones and commercialization of pamiparib, and BeiGene's plans, commitments, aspirations and goals under the headings "BeiGene Oncology" and "About BeiGene". 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 medicines and drug candidates, if approved; BeiGene's ability to obtain and maintain protection of intellectual property for its medicines and technology; BeiGene's reliance on third parties to conduct drug development, manufacturing and other services; BeiGene's limited experience in obtaining regulatory approvals and commercializing pharmaceutical products and its ability to obtain additional funding for operations and to complete the development and commercialization of its drug candidates and achieve and maintain profitability; the impact of the COVID-19 pandemic on the BeiGene's clinical development, regulatory, commercial, and other operations, 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 or Vivian Ni

+1 857-302-5663 or +1 857-302-7596

media@beigene.com

---

[i] Bray F, Ferlay J, Soerjomataram I, Siegel RL, Torre LA, Jemal A. Global cancer statistics 2018: GLOBOCAN estimates of incidence and mortality worldwide for 36 cancers in 185 countries. CA Cancer J Clin. 2018;68(6):394-424.

[ii] Torre LA, Trabert B, DeSantis CE, et al. Ovarian cancer statistics, 2018. CA Cancer J Clin. 2018;68(4):284-296.

[iii] Ovarian Cancer Research Alliance. Available at: https://ocrahope.org/patients/about-ovarian-cancer/recurrence/. Accessed April 2021.

[iv] Chen W, Zheng R, Baade PD, et al. Cancer statistics in China, 2015[J]. CA Cancer J Clin, 2016;66(2):115-132.

[v] Jiang X, Tang H, Chen T. Epidemiology of gynecologic cancers in China. J Gynecol Oncol. 2018;29(1):e7.