UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Form 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event Reported): June 4, 2021

BEIGENE, LTD.
(Exact Name of Registrant as Specified in Charter)

Cayman Islands	**001-37686**	**98-1209416**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(I.R.S. Employer Identification Number)

c/o Mourant Governance Services (Cayman) Limited
94 Solaris Avenue, Camana Bay
Grand Cayman KY1-1108
Cayman Islands
(Address of Principal Executive Offices) (Zip Code)

+1 (345) 949-4123
(Registrant's telephone number, including area code)

Not Applicable
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
American Depositary Shares, each representing 13 Ordinary Shares, par value $0.0001 per share	**BGNE**	**The NASDAQ Global Select Market**
Ordinary Shares, par value $0.0001 per share*	**06160**	**The Stock Exchange of Hong Kong Limited**

*Included in connection with the registration of the American Depositary Shares with the Securities and Exchange Commission. The ordinary shares are not registered or listed for trading in the United States but are listed for trading on The Stock Exchange of Hong Kong Limited.

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2). Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. o

Item 8.01. Other Events.

On June 4, 2021, BeiGene, Ltd. (the “Company” or “BeiGene”) announced clinical data from two pivotal trials of its anti-PD-1 antibody tislelizumab at the 2021 American Society of Clinical Oncology Annual Meeting (ASCO 2021), including the Phase 3 RATIONALE 302 trial of tislelizumab compared to chemotherapy in previously treated patients with advanced or metastatic esophageal squamous carcinoma and the pivotal Phase 2 trial of tislelizumab in patients with previously treated, locally advanced unresectable or metastatic microsatellite instability-high or mismatch-repair-deficient solid tumors. ASCO 2021 takes place virtually on June 4-8, 2021. The full text of this press release is filed as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

On June 4, 2021, the Company announced that its PARP inhibitor pamiparib showed efficacy in patients with HER2-negative breast cancer and demonstrated numerically higher but not statistically significant progression-free survival in gastric cancer. The results in gastric cancer may have been influenced by the fact that the study did not meet the planned enrollment target. These data were presented in poster sessions at the ASCO 2021, and included initial reporting from a Phase 2 trial evaluating pamiparib in locally advanced or metastatic HER2-negative breast cancer with germline BRCA1/2 mutation and initial reporting of a randomized Phase 2 trial of pamiparib as maintenance therapy in patients with inoperable locally advanced or metastatic gastric cancer who responded to platinum-based first-line chemotherapy. The full text of this press release is filed as Exhibit 99.2 to this Current Report on Form 8-K and is incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release titled "BeiGene Presents Clinical Data from Two Pivotal Trials of Tislelizumab at the 2021 ASCO Annual Meeting", issued by BeiGene, Ltd. on June 4, 2021.
99.2	Press Release titled "BeiGene Presents Clinical Data from Two Phase 2 Trials of Pamiparib at the 2021 ASCO Annual Meeting", issued by BeiGene, Ltd. on June 4, 2021.
104	The cover page from this Current Report on Form 8-K, formatted in Inline XBRL

Exhibit Index

Exhibit No.	Description
99.1	Press Release titled "BeiGene Presents Clinical Data from Two Pivotal Trials of Tislelizumab at the 2021 ASCO Annual Meeting", issued by BeiGene, Ltd. on June 4, 2021.
99.2	Press Release titled "BeiGene Presents Clinical Data from Two Phase 2 Trials of Pamiparib at the 2021 ASCO Annual Meeting", issued by BeiGene, Ltd. on June 4, 2021.
104	The cover page from this Current Report on Form 8-K, formatted in Inline XBRL

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

BEIGENE, LTD.

Date: June 4, 2021

By: /s/ Scott A. Samuels
Name: Scott A. Samuels
Title: Senior Vice President, General Counsel

Exhibit 99.1

BeiGene Presents Clinical Data from Two Pivotal Trials of Tislelizumab at the 2021 ASCO Annual Meeting

Compared to chemotherapy, tislelizumab demonstrated a statistically significant and clinically meaningful improvement in overall survival in patients with previously treated, advanced or metastatic esophageal squamous carcinoma and a favorable safety profile

Tislelizumab also demonstrated a statistically significant and clinically meaningful improvement in overall response rate in patients with MSI-H or dMMR solid tumors and was generally well tolerated

CAMBRIDGE, Mass. and BEIJING, China, June 4, 2021 -- BeiGene, Ltd. (NASDAQ: BGNE; HKEX: 06160), a global biotechnology company focused on developing and commercializing innovative medicines worldwide, today announced clinical data from two pivotal trials of its anti-PD-1 antibody tislelizumab at the 2021 American Society of Clinical Oncology Annual Meeting (ASCO 2021), including the Phase 3 RATIONALE 302 trial of tislelizumab compared to chemotherapy in previously treated patients with advanced or metastatic esophageal squamous carcinoma (ESCC) and the pivotal Phase 2 trial of tislelizumab in patients with previously treated, locally advanced unresectable or metastatic microsatellite instability-high (MSI-H) or mismatch-repair-deficient (dMMR) solid tumors. ASCO 2021 takes place virtually on June 4-8, 2021.

“We are delighted to share the promising results from two pivotal trials of tislelizumab at this year’s ASCO, RATIONALE 302 in ESCC and a pivotal Phase 2 trial in MSI-H or dMMR solid tumors, which we plan to discuss with health authorities,” commented Yong (Ben) Ben, M.D., Chief Medical Officer, Immuno-Oncology at BeiGene. “We and our collaborator Novartis are committed to advancing tislelizumab in a broad global clinical program both as a monotherapy and in combination with other cancer therapeutics. We hope that, with a growing body of clinical evidence, tislelizumab can become a meaningful immunotherapy that can potentially benefit more patients worldwide.”

Primary Results of RATIONALE 302 Trial of Tislelizumab vs. Chemotherapy in Previously Treated Advanced or Metastatic ESCC

Poster No. 4012

RATIONALE 302 is a randomized, open-label, multicenter global Phase 3 trial (NCT03430843) designed to evaluate the efficacy and safety of tislelizumab when compared to investigator’s choice chemotherapy as a second-line treatment for patients with advanced or metastatic ESCC. The primary endpoint is overall survival (OS) in the intent-to-treat (ITT) population; a key secondary endpoint is OS in patients with high PD-L1 expression (defined as visually-estimated combined positive score [vCPS] ≥10%); and other secondary endpoints include progression-free survival (PFS), objective response rate (ORR), duration of response (DoR), and safety. A total of 512 patients were enrolled in the trial in 11 countries or regions across Asia, Europe, and North America, randomized 1:1 to either the tislelizumab arm or the chemotherapy arm (investigator’s choice of paclitaxel, docetaxel, or irinotecan).

“Advanced or metastatic ESCC typically has a poor prognosis, with the five-year survival rate estimated at five percent. In the RATIONALE 302 trial, tislelizumab significantly prolonged survival for these patients with consistent survival benefit observed across pre-defined subgroups, including PD-L1 expression and patient race,” commented Lin Shen, M.D., Peking University Cancer Hospital and Institute and a principal investigator of the trial. “In addition, tislelizumab demonstrated a favorable safety profile compared to chemotherapy, with no new safety signals identified. We hope that this anti-PD-1 antibody can become a new treatment option for those with advanced or metastatic ESCC following prior systemic treatment.”

At the data cutoff on December 1, 2020, the median follow-up time in the tislelizumab arm and the chemotherapy arm was 8.5 months and 5.8 months, respectively.

Tislelizumab demonstrated a statistically significant and clinically meaningful improvement in OS, compared to chemotherapy, in both the ITT population (primary endpoint) and in patients with high PD-L1 expression (key secondary endpoint). Efficacy results included:

- In the ITT population, the median OS in the tislelizumab arm was 8.6 months (95% CI: 7.5, 10.4), compared to 6.3 months (95% CI: 5.3, 7.0) in the chemotherapy arm (p=0.0001; hazard ratio [HR]=0.70 [95% CI: 0.57, 0.85]). The OS rates at six months and 12 months were 62.3% and 37.4% in the tislelizumab arm, respectively, compared to 51.8% and 23.7% in the chemotherapy arm;

- In patients with high PD-L1 expression, the median OS in the tislelizumab arm was 10.3 months (95% CI: 8.5, 16.1), compared to 6.8 months (95% CI: 4.1, 8.3) in the chemotherapy arm (p=0.0006; HR=0.54 [95% CI: 0.36, 0.79]). The OS rates at six months and 12 months were 67.4% and 44.0% in the tislelizumab arm, respectively, compared to 50.8% and 27.0% in the chemotherapy arm;

- In the trial, the PFS curves for two arms separate late. The median PFS was 1.6 months (95% CI: 1.4, 2.7) in the tislelizumab arm, compared to 2.1 months (95% CI: 1.5, 2.7) in the chemotherapy arm (HR=0.83 [95% CI: 0.67, 1.01]). The PFS rates at six months and 12 months were 21.7% and 12.7% in the tislelizumab arm, compared to 14.9% and 1.9% in the chemotherapy arm;

- Tislelizumab was associated was a higher ORR of 20.3% (95% CI: 15.6, 25.8), compared to 9.8% (95% CI: 6.4, 14.1) on chemotherapy, and

- Tislelizumab demonstrated a more durable anti-tumor response, with a median DoR of 7.1 months (95% CI: 4.1, 11.3), compared to 4.0 months (95% CI: 2.1, 8.2) on chemotherapy.

Compared to chemotherapy, tislelizumab demonstrated a favorable safety profile with no new safety signals identified. Safety results included:

- 244 patients (95.7%) experienced at least one treatment-emergent adverse event (TEAE) of any grade in the tislelizumab arm, compared to 236 patients (98.3%) in the chemotherapy arm;

- In the tislelizumab arm, 187 patients (73.3%) experienced at least one treatment-related adverse event (TRAE) of any grade, with the most common (≥10%) being aspartate aminotransferase (AST) increased (11.4%), anemia (11.0%), and hypothyroidism (10.2%);

- In the chemotherapy arm, 225 patients (93.8%) experienced at least one TRAE of any grade, with the most common (≥10%) being white blood cell count decreased (40.8%), neutrophil count decreased (39.2%), anemia (34.6%), decreased appetite (31.3%), diarrhea (27.5%), nausea (27.5%), vomiting (17.9%), alopecia (17.5%), malaise (14.6%), fatigue (13.8%), neutropenia (12.9%), leukopenia (12.5%), asthenia (11.7%), constipation (10.4%), and weight decreased (10.4%);

- Grade ≥3 TEAEs and TRAEs were reported in 118 patients (46.3%) and 48 patients (18.8%) in the tislelizumab arm, compared to 163 patients (67.9%) and 134 patients (55.8%) in the chemotherapy arm;

- Serious TEAEs and TRAEs were reported in 105 patients (41.2%) and 36 patients (14.1%) in the tislelizumab arm, compared to 105 patients (43.8%) and 47 patients (19.6%) in the chemotherapy arm;

- TEAEs or TRAEs leading to treatment discontinuation occurred in 49 patients (19.2%) and 17 patients (6.7%) in the tislelizumab arm, compared to 64 patients (26.7%) and 33 patients (13.8%) in the chemotherapy arm; and

- Death due to TEAEs or TRAEs occurred in 14 patients (5.5%) and five patients (2.0%) in the tislelizumab arm, compared to 14 patients (5.8%) and seven patients (2.9%) in the chemotherapy arm.

Results from Pivotal Phase 2 Trial in MSI-H or dMMR Solid Tumors

Poster No. 2569

This single-arm, open-label, multicenter pivotal Phase 2 trial (NCT03736889) was designed to evaluate the efficacy and safety of tislelizumab as a monotherapy in patients with previously treated, locally advanced unresectable or metastatic MSI-H or dMMR solid tumors, with an enrollment of 80 patients in China. The primary endpoint of this trial is ORR as assessed by independent review committee (IRC) per RECIST v1.1; secondary endpoints include time to response (TTR), DoR, disease control rate (DCR), and PFS as assessed by investigator and IRC, OS, and safety and tolerability.

“MSI-H and dMMR are found in many solid tumors, in particular cancers of the gastrointestinal tract, and existing literature supports a tissue-agnostic treatment approach with checkpoint inhibitors,” said Jian Li, M.D., Beijing Cancer Hospital and a principal investigator of the trial. “In this pivotal Phase 2 trial, we observed consistent responses across tumor types with tislelizumab and it was generally well tolerated. We will continue patient follow-up for longer term evaluation, and hope that tislelizumab could potentially become a new treatment option for patients with MSI-H/dMMR solid tumors.”

At the data cutoff on December 7, 2020, the median follow-up time was 11.78 months. Seventy-four patients were included in the primary efficacy analysis set, including 46 patients (62.2%) with colorectal cancer (CRC) and 28 patients with endometrial cancer, gastric or gastroesophageal junction (G/GEJ) cancer, and other tumor types.

Tislelizumab demonstrated a statistically significant and durable anti-tumor activity and showed consistent efficacy across tumor types, demonstrating the benefit of tissue-agnostic treatment. Efficacy results included:

- The ORR as assessed by IRC was 45.9% (95% CI: 34.3, 57.9; $p<0.0001$) in the primary efficacy analysis set, 39.1% (95% CI: 25.1, 54.6) in patients with CRC, 57.1% (95% CI: 37.2, 75.5) in patients with other tumor types;
- Four patients (5.4%) achieved a complete response (CR), including two (4.3%) with CRC, of which one was a patient with G/GEJ cancer and the other was a patient with endometrial cancer;
- Among the 34 patients (45.9%) who achieved a response, the median TTR was 10.5 weeks with no report of progressive disease; except for one patient who started new therapy, 33 of these patients still had an ongoing response with a DoR rate of 100% at 12 months, but the median DoR was not reached; and
- The median PFS and OS were not reached, and the PFS rate and OS rate at 12 months were 59.3% (95% CI: 46.2, 70.2) and 75.3% (95% CI: 62.6, 84.2), respectively, and consistent between patients with CRC and patients with other tumor types;

In the safety analysis set of all 80 patients, tislelizumab was generally well tolerated with no new safety signals identified. Safety results were consistent with expected manifestations of the disease and known effects of anti-PD-1 antibodies, including:

- 80 patients (100%) experienced at least one TEAE of any grade; and 79 patients (98.8%) experienced at least one TRAE of any grade, with the most common (≥15%) being anemia (43.8%), alanine aminotransferase (ALT) increased (28.8%), blood bilirubin increased (25.0%), AST increased (23.8%), white blood cell count decreased (22.5%), hypothyroidism (18.8%), rash (18.8%), and neutrophil count decreased (15.0%);
- Grade ≥3 TEAEs and TRAEs were reported in 38 patients (47.5%) and 34 patients (42.5%), respectively;
- Serious TEAEs and TRAEs were reported in 27 patients (33.8%) and 21 patients (26.3%), respectively;
- Treatment discontinuation due to TEAEs and TRAEs each occurred in four patients (5.0%); and
- Death due to TEAEs and TRAEs occurred in five patients (6.3%) and three patients (3.8%), respectively.

To learn more about BeiGene's research and development and activities around ASCO, please visit https://beigenevirtualexperience.com/.

About Tislelizumab

Tislelizumab (BGB-A317) is a 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 from BeiGene's immuno-oncology biologics program and is being developed internationally as a monotherapy and in combination with other therapies for the treatment of a broad array of both solid tumor and hematologic cancers.

The China National Medical Products Administration (NMPA) has granted tislelizumab approval in three indications, including full approval for first-line treatment of patients with advanced squamous non-small cell lung cancer (NSCLC) in combination with chemotherapy; and conditional approval for the treatment of patients with classical Hodgkin's lymphoma (cHL) who received at least two prior therapies and for the treatment of patients with locally advanced or metastatic urothelial carcinoma (UC) with PD-L1 high expression whose disease progressed during or following platinum-containing chemotherapy or within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy. Full approval for these indications is contingent upon results from ongoing randomized, controlled confirmatory clinical trials.

In addition, three supplemental Biologics License Applications for tislelizumab have been accepted by the Center for Drug Evaluation (CDE) of the NMPA and are under review for first-line treatment of patients with advanced non-squamous NSCLC in combination with chemotherapy, for second- or third-line treatment of patients with locally advanced or metastatic NSCLC who progressed on prior platinum-based chemotherapy, and for patients with previously treated with at least one systemic therapy hepatocellular carcinoma.
BeiGene has initiated or completed 17 potentially registration-enabling clinical trials in China and globally, including 13 Phase 3 trials and four pivotal Phase 2 trials.

In January 2021, BeiGene and Novartis entered into a collaboration and license agreement granting Novartis rights to develop, manufacture, and commercialize tislelizumab in North America, Europe, and Japan.

Tislelizumab is not approved for use outside of China.

About the Tislelizumab Clinical Program

Clinical trials of tislelizumab include:

- Phase 3 trial comparing tislelizumab with docetaxel in the second- or third-line setting in patients with NSCLC (NCT03358875);
- Phase 3 trial comparing tislelizumab to salvage chemotherapy in patients with relapsed or refractory classical Hodgkin Lymphoma (cHL; NCT04486391);
- Phase 3 trial in patients with locally advanced or metastatic urothelial carcinoma (NCT03967977);
- Phase 3 trial of tislelizumab in combination with chemotherapy versus chemotherapy as first-line treatment for patients with advanced squamous NSCLC (NCT03594747);
- Phase 3 trial of tislelizumab in combination with chemotherapy versus chemotherapy as first-line treatment for patients with advanced non-squamous NSCLC (NCT03663205);
- Phase 3 trial of tislelizumab in combination with platinum-based doublet chemotherapy as neoadjuvant treatment for patients with NSCLC (NCT04379635);
- Phase 3 trial of tislelizumab combined with platinum and etoposide versus placebo combined with platinum and etoposide in patients with extensive-stage small cell lung cancer (NCT04005716);
- Phase 3 trial comparing tislelizumab with sorafenib as first-line treatment for patients with hepatocellular carcinoma (HCC; NCT03412773);
- Phase 2 trial in patients with previously treated unresectable HCC (NCT03419897);
- Phase 2 trial in patients with locally advanced or metastatic urothelial bladder cancer (NCT04004221);
- Phase 3 trial comparing tislelizumab with chemotherapy as second-line treatment for patients with advanced esophageal squamous cell carcinoma (ESCC; NCT03430843);
- Phase 3 trial of tislelizumab in combination with chemotherapy as first-line treatment for patients with ESCC (NCT03783442);
- Phase 3 trial of tislelizumab versus placebo in combination with chemoradiotherapy in patients with localized ESCC (NCT03957590);
- Phase 3 trial of tislelizumab combined with chemotherapy versus placebo combined with chemotherapy as first-line treatment for patients with gastric cancer (NCT03777657);
- Phase 2 trial of tislelizumab in patients with relapsed or refractory cHL (NCT03209973);
- Phase 2 trial in patients with MSI-H/dMMR solid tumors (NCT03736889); and

- Phase 3 trial of tislelizumab combined with chemotherapy versus placebo combined with chemotherapy as first-line treatment in patients with nasopharyngeal cancer (NCT03924986).

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 for patients across the globe. We have a growing R&D team of approximately 2,300 colleagues dedicated to advancing more than 90 clinical trials involving more than 13,000 patients and healthy volunteers. 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 three 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 and PARP inhibitor pamiparib 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 clinical trials of tislelizumab presented in this press release, the potential for tislelizumab to provide clinical benefit or advantages in safety and tolerability to patients, BeiGene's advancement, anticipated clinical development, regulatory milestones and commercialization of tislelizumab, 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 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	Media Contact
Craig West	Liza Heapes or Vivian Ni
+1 857-302-5189	+1 857-302-5663 or + 1 857-302-7596
ir@beigene.com	media@beigene.com

Exhibit 99.2

BeiGene Presents Clinical Data from Two Phase 2 Trials of Pamiparib at the 2021 ASCO Annual Meeting

Pamiparib, a potent and selective PARP1 and PARP2 inhibitor, demonstrated meaningful and durable efficacy in patients with advanced HER2-negative breast cancer

Pamiparib showed numerically higher progression-free survival in patients with gastric cancer compared to placebo, although the results did not achieve statistical significance

Pamiparib was generally well-tolerated across both trials

Pamiparib was recently approved in China for the treatment of patients with previously treated advanced ovarian cancer

CAMBRIDGE, Mass. and BEIJING, China, June 4, 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 showed efficacy in patients with HER2-negative breast cancer and demonstrated numerically higher but not statistically significant progression-free survival in gastric cancer. The results in gastric cancer may have been influenced by the fact that the study did not meet the planned enrollment target. These data were presented in poster sessions at the 2021 American Society of Clinical Oncology Annual Meeting (ASCO 2021) taking place virtually on June 4-8, 2021, and included initial reporting from a Phase 2 trial evaluating pamiparib in locally advanced or metastatic HER2-negative (HER2[-]) breast cancer with germline *BRCA1/2* mutation (g*BRCA1/2*m) and initial reporting of a randomized Phase 2 trial of pamiparib as maintenance therapy in patients with inoperable locally advanced or metastatic gastric cancer who responded to platinum-based first-line chemotherapy.

“We are pleased to share results from our pamiparib clinical development program, focused on diseases with high prevalence, as we work towards our mission of improving outcomes for patients in need,” commented Yong (Ben) Ben, M.D., Chief Medical Officer, Immuno-Oncology at BeiGene. “We are encouraged by the positive results for pamiparib in HER2-negative breast cancer, a devastating disease and leading cause of cancer death among women, and while it did not achieve statistical significance in gastric cancer, we hope these findings can improve understanding among the scientific community and reinforce the tolerability of pamiparib as we advance its global development.”

Results from Phase 2 Trial of Pamiparib in Locally Advanced or Metastatic HER2-Negative Breast Cancer with g*BRCA*m

Poster No. 1087

This single-arm, open label, multi-center Phase 2 trial (NCT03575065) was designed to evaluate the safety and efficacy of pamiparib in patients with locally advanced or metastatic HER2-negative breast cancer, with deleterious or suspected deleterious g*BRCA1/2*m, who received no more than two prior lines of chemotherapy. A total of 88 patients were enrolled, including 62 patients with triple-negative breast cancer (TNBC cohort) and 26 patients with hormone receptor-positive (HR[+]) and HER2(-) breast cancer (HR[+] cohort). Fifty-five patients in the TNBC cohort and 21 patients in the HR(+) cohort had measurable disease at baseline per independent review committee (IRC). The primary endpoint of the trial was objective response rate (ORR) as assessed by IRC per RECIST v1.1; secondary endpoints included investigator-assessed ORR, duration of response (DoR), best overall response (BOR), progression-free survival (PFS), clinical benefit rate (CBR), and disease control rate (DCR) as assessed by IRC and investigator, and overall survival (OS), as well as safety and tolerability.

“Studies have suggested that breast cancer with germline *BRCA* mutations may be susceptible to PARP inhibition. These Phase 2 results demonstrated pamiparib’s efficacy in patients with HR(+)/HER2(-) breast cancer, as well as in triple-negative breast cancer, one of the most aggressive forms of the disease with the poorest outcomes,” said Binghe Xu, M.D., Ph.D., Cancer Hospital Chinese Academy of Medical Sciences and a principal investigator of the trial. “In addition to demonstrating positive response rates, the trial suggested pamiparib may show promise in progression-free survival benefits and we look forward to further research of pamiparib in this patient population, who are in great need of additional treatment options.”

At the data cut-off on October 9, 2020, the median follow-up time was 13.8 months (TNBC cohort, 10.9 months; HR[+] cohort, 18.5 months).

Pamiparib demonstrated meaningful and durable clinical activity in patients across both cohorts. Efficacy results included:

- Confirmed ORR as assessed by IRC, the primary efficacy endpoint, was 61.9% (95% CI: 38.4, 81.9) in the HR(+) cohort and 38.2% (95% CI: 25.4, 52.3) in the TNBC cohort;
- Four patients achieved a complete response (CR), including three in the TNBC cohort and one patient in the HR(+) cohort;
- 18 patients in the TNBC cohort and 12 patients in the HR(+) cohort demonstrated a partial response (PR);
- DCR as assessed by IRC was 90.5% (95% CI: 69.6, 98.8) in the HR(+) cohort and 72.7% (95% CI: 59.0, 83.9) in the TNBC cohort;
- Additionally, CBR as assessed by IRC was 71.4% (95% CI: 47.8, 88.7) in the HR(+) cohort and 43.6% (95% CI: 30.3, 57.7) in the TNBC cohort;
- Patients in the HR(+) cohort had a median DoR of 7.5 months (95% CI: 5.6, 14.8) and patients in the TNBC cohort had a median DoR of 7.0 months (95% CI: 3.9, not estimable [NE]);
- The median PFS was 9.2 months (95% CI: 7.4, 11.9) in the HR(+) cohort and 5.5 months (95% CI: 3.7, 7.3) in the TNBC cohort; and
- In the trial, the median OS in the TNBC cohort was 17.1 months (95% CI:13.7, NE) and was not reached in the HR(+) cohort (NE; 95% CI: 18.1, NE).

Pamiparib was generally well-tolerated, and results from the safety analysis for all 88 patients across both cohorts included:

- 87 patients (98.9%) experienced at least one treatment-emergent adverse event (TEAE) of any grade and 54 patients (61.4%) experienced at least one Grade ≥3 TEAE;
- 87 patients (98.9%) experienced at least one treatment-related TEAE of any grade, and 53 patients (60.2%) experienced at least one Grade ≥3 treatment-related TEAE, with the most common (≥5%) being anemia (39.8%), neutrophil count decrease (29.5%), white blood cell count decrease (21.6%), platelet count decrease (9.1%), leukopenia (5.7%), and neutropenia (5.7%);
- Serious TEAEs were reported in 19 patients (21.6%) and serious treatment-related TEAEs were reported in 15 patients (17.0%);
- Two patients experienced treatment discontinuation due to TEAEs, both considered treatment-related; and
- TEAEs leading to death occurred in one patient (1.1%) and no treatment-related TEAEs leading to death were reported.

Results from Phase 2 Trial of Pamiparib vs. Placebo in Locally Advanced or Metastatic Gastric Cancer

Poster No. 3109

PARALLEL 303 is a double-blind, randomized, multicenter Phase 2 trial (NCT03427814) comparing the safety and efficacy of pamiparib vs placebo as maintenance therapy in patients with inoperable locally advanced or metastatic gastric cancer that responded to platinum-based first-line chemotherapy. A total of 136 patients were enrolled and due to slow enrollment and a change in the standard of care for this patient population, the trial did not meet the planned target enrollment of approximately 540 patients. Patients were randomized 1:1 to receive pamiparib 60 mg orally twice daily (n = 71) or placebo (n = 65) in 28-day cycles. The primary endpoint was PFS as assessed by investigator per RECIST v1.1; secondary endpoints included time to subsequent treatment (TSST), ORR, DoR, and time to response (TTR) as assessed by investigator, OS, and safety. At the time of data analysis, OS data were immature.

“Many patients with gastric cancer become resistant to currently available therapies in later stages of disease, so continued research is crucial to find medicines that may improve outcomes and survival,” said Fortunato Ciardiello, M.D., Ph.D., Second University of Naples, Italy and a principal investigator of the trial. “Though the PARALLEL 303 study did not achieve statistical significance, these results help us advance understanding of the role that PARP inhibition has in metastatic gastric cancer and reinforces pamiparib’s safety profile and potential clinical benefit for appropriate patients.”

At the data cutoff on December 7, 2020, median follow-up time was 8.0 months (pamiparib arm, 7.9 months; placebo arm, 8.0 months).

Pamiparib demonstrated a numerically higher median PFS of 3.7 months (95% CI, 1.9, 5.3 months), compared to 2.1 months (95% CI, 1.9, 3.8 months) in the placebo arm, however the trial did not achieve statistical significance (p=0.1428; HR=0.799 [95% CI, 0.5, 1.2]). Additional efficacy results included:

- The median OS in the pamiparib arm was 10.2 months (95% CI: 8.7, 16.3), compared to 12.0 months in the placebo arm (95% CI: 8.2, not estimable [NE]);
- The ORR in the pamiparib arm was 7.7% (95% CI: 1.6, 20.9), compared to 6.3% (95% CI: 0.8, 20.8) in the placebo arm;
- The median DoR in the pamiparib arm was 3.6 months (95% CI: 3.5, NE), compared to NE (95% CI: 5.6, NE) in the placebo arm; and
- The median TTR in the pamiparib arm was 3.7 months (range: 1.8, 7.3), compared to 1.9 months (range: 1.9, 1.9) in the placebo arm.

In the trial, pamiparib was generally well-tolerated, with no new safety signals observed. Safety results included:

- 65 patients (91.5%) experienced at least one TEAE of any grade in the pamiparib arm, compared to 61 patients (93.8%) in the placebo arm;
- Serious TEAEs and TEAEs of Grade ≥3 were reported in 14 patients (19.7%) and 29 patients (40.8%) respectively in the pamiparib arm, compared to 10 patients (15.4%) and 20 patients (30.8%) in the placebo arm;
- In the pamiparib arm, the most common (≥10%) TEAEs included anemia (36.6%), nausea (32.4%), decreased appetite (26.8%), vomiting (23.9%), asthenia (21.1%), diarrhea (18.3%), upper abdominal pain (16.9%), aspartate aminotransferase increased (AST; 12.7%), alanine aminotransferase increased (ALT; 11.3%), abdominal pain (11.3%), constipation (11.3%), and white blood cell count decreased (11.3%);
- In the placebo arm, the most common (≥10%) TEAEs included abdominal pain (18.5%), nausea (16.9%), peripheral sensory neuropathy (13.8%), asthenia (16.9%), anemia (12.3%), decreased appetite (12.3%), dysphagia (12.3%), upper abdominal pain (10.8%), constipation (10.8%), and diarrhea (10.8%);
- Treatment discontinuation due to TEAEs occurred in eight patients (11.3%) in the pamiparib arm, compared to two patients (3.1%) in the placebo arm; and
- Death due to TEAEs occurred in two patients (2.8%) in the pamiparib arm, none of which were deemed treatment-related, compared to two patients (3.1%) in the placebo arm, of which one (1.5%) was deemed treatment-related.

To learn more about BeiGene’s research and development and activities around ASCO, please visit https://beigenevirtualexperience.com/.

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 the treatment of patients with germline *BRCA* (g*BRCA*) 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 for patients across the globe. We have a growing R&D team of approximately 2,300 colleagues dedicated to advancing more than 90 clinical trials involving more than 13,000 patients and healthy volunteers. 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 three 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 and PARP inhibitor pamiparib 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 clinical trials of pamiparib presented in this press release, the potential for pamiparib to provide clinical benefit or advantages in safety and tolerability 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 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	Media Contact
Craig West	Liza Heapes or Vivian Ni
+1 857-302-5189	+1 857-302-5663 or + 1 857-302-7596
ir@beigene.com	media@beigene.com