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): April 15, 2022

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 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. ☐

Item 7.01. Regulation FD Disclosure.

BeiGene, Ltd. (the "Company") expects to announce its financial results for the three months ended March 31, 2022 before the open of U.S. financial markets on Thursday May 5, 2022.

Item 8.01. Other Events.

On April 15, 2022, the Company issued a press release announcing that the China National Medical Products Administration (NMPA) has granted approval to BeiGene's anti-PD-1 antibody, tislelizumab, as a treatment for patients with locally advanced or metastatic esophageal squamous cell carcinoma (ESCC) who have disease progression or are intolerant to first-line standard chemotherapy. A copy of this press release is attached hereto as Exhibit 99.1, and is incorporated herein by reference.

On April 19, 2022, the Company issued a press release announcing the presentation of updated data analyses from the Phase 3 RATIONALE-309 trial of tislelizumab, a humanized anti-PD-1 monoclonal antibody, in combination with chemotherapy versus chemotherapy plus placebo as a first-line treatment for patients with recurrent or metastatic nasopharyngeal cancer (RM-NPC), at the virtual American Society of Clinical Oncology (ASCO) Plenary Series on April 19, 2022. A copy of this press release is attached hereto as Exhibit 99.2, and is incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press release titled "China NMPA Approves Tislelizumab for Patients with Second-Line Esophageal Squamous Cell Carcinoma" issued by BeiGene, Ltd. on February 15, 2022.
99.2	Press release titled "BeiGene Presents Updated Results from Phase 3 RATIONALE-309 Trial of PD-1 Inhibitor Tislelizumab in First-Line RM-NPC in Virtual ASCO Plenary Series" issued by BeiGene, Ltd. on February 19, 2022.
104	The cover page from this Current Report on Form 8-K, formatted in Inline XBRL

Exhibit Index

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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: April 20, 2022

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

Exhibit 99.1

China NMPA Approves Tislelizumab for Patients with Second-Line Esophageal Squamous Cell Carcinoma

Tislelizumab is now approved for eight indications in China

CAMBRIDGE, Mass. & BASEL, Switzerland & BEIJING-- BeiGene, Ltd. (NASDAQ: BGNE; HKEX: 06160; SSE: 688235), a global, science-driven biotechnology company focused on developing innovative and affordable medicines to improve treatment outcomes and access for patients worldwide, today announced that the China National Medical Products Administration (NMPA) has granted approval to BeiGene's anti-PD-1 antibody, tislelizumab, as a treatment for patients with locally advanced or metastatic esophageal squamous cell carcinoma (ESCC) who have disease progression or are intolerant to first-line standard chemotherapy.

"As a second-line treatment for patients with ESCC, this differentiated checkpoint inhibitor demonstrated significant improvements in overall survival and was generally well-tolerated in our Phase 3 trial of tislelizumab," commented Mark Lanasa, M.D., Ph.D., Senior Vice President, Chief Medical Officer, Solid Tumors, at BeiGene. "Tislelizumab regulatory submissions in this indication submitted by Novartis are under review by the U.S. FDA and the European Medicines Agency, highlighting our commitment to advancing its progress on behalf of the many patients around the world with ESCC and other forms of cancer."

"With eight approved indications in China, our science-based commercial team of more than 3,100+ professionals is working to make tislelizumab more broadly available to those in China who may benefit from this important immunotherapy," commented Xiaobin Wu, Ph.D., President, Chief Operating Officer, and General Manager of China, at BeiGene. "Today's approval is a great step for patients in China with ESCC."

"The NMPA's approval of tislelizumab is welcome news to patients with previously treated ESCC, for whom we are pleased to now be able to provide this new treatment option," said Lin Shen, Vice President of Clinical Oncology, Beijing Cancer Hospital, and the principal investigator of the trial. "The global Phase 3 clinical trial of tislelizumab demonstrated positive safety and efficacy outcomes as a second-line treatment for patients with ESCC, one of the most common malignant tumors in the digestive tract."

This approval was supported by clinical results from a randomized, open-label, multi-center, global Phase 3 clinical trial, RATIONALE 302 (NCT03430843), to evaluate the efficacy and safety of tislelizumab as a second-line treatment for patients with locally advanced or metastatic ESCC compared to chemotherapy. The primary endpoint of this trial 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 and regions in Asia, Europe, and North America, randomized 1:1 to either the tislelizumab arm or chemotherapy arm (investigator's choice of paclitaxel, docetaxel, or irinotecan). Results of this trial were presented at the 2021 American Society of Clinical Oncology (ASCO) Annual Meeting.

Tislelizumab is also under regulatory review in the U.S. and the European Union, submitted by Novartis in their licensed territories, as a second-line treatment for patients with locally advanced or metastatic ESCC.

About Esophageal Squamous Cell Carcinoma (ESCC)

Esophageal cancer is one of the most common malignant tumors in the digestive tract. As a country with a high incidence of esophageal cancer, China accounts for 53.7% of the world's new cases of esophageal cancer and 55.7% of the world's deaths every year.[i] Esophageal cancer is mainly divided into squamous cell cancer and adenocarcinoma. Esophageal squamous cell cancer is the dominant cancer worldwide (approximately 90%), and it accounts for more than 90% of esophageal cancer patients in China.[ii]

About Tislelizumab

Tislelizumab is an anti-programmed death receptor-1 (PD-1) inhibitor designed to help aid the body's immune cells to detect and fight tumors. Tislelizumab, a humanized monoclonal antibody, is 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. BeiGene has initiated or completed more than 20 potentially registration-enabling clinical trials in 35 countries and regions, including 17 Phase 3 trials and four pivotal Phase 2 trials.

Tislelizumab is approved by the China National Medical Products Administration (NMPA) as a treatment for eight indications, including multiple approvals in non-small cell lung cancer (NSCLC). Tislelizumab has been submitted for regulatory review in one additional indication in China and as a potential treatment for unresectable recurrent locally advanced or metastatic ESCC after prior systemic therapy in the U.S., and in NSCLC and ESCC in Europe. In January 2021, BeiGene announced a collaboration with Novartis to accelerate the clinical development and marketing of tislelizumab in North America, Europe and Japan.
Tislelizumab is not approved for use outside of China.

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 and medical affairs team of approximately 2,900 colleagues dedicated to advancing more than 100 clinical trials that have involved more than 14,500 subjects. Our expansive portfolio is directed predominantly by our internal colleagues supporting clinical trials in more than 45 countries and regions. 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. BeiGene currently has three approved medicines discovered and developed in our own labs: BTK inhibitor BRUKINSA® in the U.S., China, the EU and U.K., Canada, Australia and additional international markets; and the non-FC-gamma receptor binding anti-PD-1 antibody tislelizumab as well as the 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, Bristol Myers Squibb, EUSA Pharma and Bio-Thera. We also plan to address greater areas of unmet need globally through our other collaborations including with Mirati Therapeutics, Seagen, and Zymeworks.

In January 2021, BeiGene and Novartis announced a collaboration granting Novartis rights to co-develop, manufacture, and commercialize BeiGene's anti-PD1 antibody, tislelizumab, in North America, Europe, and Japan. Building upon this productive collaboration, including a biologics license application (BLA) under U.S Food and Drug Administration (FDA) review, BeiGene and Novartis announced an option, collaboration and license agreement in December 2021 for BeiGene's TIGIT inhibitor, ociperlimab, that is in Phase 3 development. Novartis and BeiGene also entered into a strategic commercial agreement through which BeiGene will promote five approved Novartis Oncology products across designated regions of China.

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 expediting development of our diverse pipeline of novel therapeutics through our own capabilities and collaborations. We are committed to radically improving access to medicines for two billion more people by 2030. BeiGene has a growing global team of over 8,000 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 global Phase 3 clinical trial RATIONALE 302, BeiGene's plans to pursue the full potential of tislelizumab and expand access where there is unmet medical need, BeiGene's efforts to make tislelizumab more broadly available in China, the potential for tislelizumab to treat patients with ESCC, 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, manufacturing and other operations, as well as those risks more fully discussed in the section entitled "Risk Factors" in BeiGene's most recent annual report on Form 10-K 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.

[i] International Agency for Research on Cancer in 2018, WHO data cancer today. https://gco.iarc.fr/today/explore

[ii] Guidelines for diagnosis and treatment of esophageal cancer in 2018, Health Commission of the people's Republic of China.

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Exhibit 99.2

BeiGene Presents Updated Results from Phase 3 RATIONALE-309 Trial of PD-1 Inhibitor Tislelizumab in First-Line RM-NPC in Virtual ASCO Plenary Series

Progression-Free Survival Benefit of Tislelizumab in Combination with Chemotherapy Sustained at Median 15.5 Month Follow-up

Secondary Survival Endpoint Findings Were Consistent with Interim Analysis

CAMBRIDGE, Mass. & BASEL, Switzerland & BEIJING-- BeiGene (NASDAQ: BGNE; HKEX: 06160; SSE: 688235), a global, science-driven biotechnology company focused on developing innovative and affordable medicines to improve treatment outcomes and access for patients worldwide, today announced the presentation of updated data analyses from the Phase 3 RATIONALE-309 trial of tislelizumab, a humanized anti-PD-1 monoclonal antibody, in combination with chemotherapy versus chemotherapy plus placebo as a first-line treatment for patients with recurrent or metastatic nasopharyngeal cancer (RM-NPC), at the virtual American Society of Clinical Oncology (ASCO) Plenary Series on April 19, 2022. Updated efficacy analyses showed that, at a median follow-up of 15.5 months, tislelizumab in combination with chemotherapy continued to demonstrate a clinically significant progression-free survival (PFS) benefit over chemotherapy alone for patients with RM-NPC. The safety profile of the tislelizumab and chemotherapy combination was generally manageable and consistent with known risks of each treatment agent.

“These updated findings further support tislelizumab in combination with chemotherapy as a potential standard-of-care first-line therapy for patients with RM-NPC,” said Mark Lanasa, Chief Medical Officer, Solid Tumors at BeiGene. “This study’s acceptance for presentation as part of the high-profile virtual ASCO Plenary Series underscores the potential for tislelizumab plus chemotherapy to be a practice-changing option for patients with this disease.”

An updated analysis of the primary endpoint (PFS) and two secondary endpoints (PFS2, OS) was performed based on the latest database cutoff as of Sept. 30, 2021. At a median follow-up of 15.5 months, patients administered a 200 mg dose of tislelizumab in combination with chemotherapy achieved a median PFS of 9.6 months (stratified hazard ratio (HR)=0.50 [CI: 0.37, 0.68]) compared to 7.4 months for patients dosed with placebo control and chemotherapy, as assessed by an independent review committee (IRC).

“In these updated findings from the RATIONALE-309 trial, tislelizumab in combination with chemotherapy continued to demonstrate PFS benefit over chemotherapy in patients with advanced nasopharyngeal carcinoma, while also showing benefit across a range of other survival endpoints,” said Li Zhang, M.D., professor at the Collaborative Innovation Center for Cancer Medicine, State Key Laboratory of Oncology in South China and Sun Yat-sen University Cancer Center, and the principal investigator for the study. “These results continue to support the potential for tislelizumab in combination with chemotherapy as a standard-of-care treatment in first-line RM-NPC.”

This trial’s cross over design allows patients from the placebo plus chemotherapy group to receive tislelizumab monotherapy after disease progression. Disease progression or death after next-line therapy (PFS2) was recorded to explore the optimal treatment sequence. For patients treated with tislelizumab plus chemotherapy, median PFS2 was not yet reached compared to 13.9 months for those treated with placebo plus chemotherapy (HR=0.38 [95% CI: 0.25, 0.58]). A positive overall survival (OS) trend was also observed with median OS not yet reached in the tislelizumab combination arm and 23 months for the chemotherapy plus placebo arm (HR=0.60 [95% CI: 0.25, 1.01]).

Biomarker analyses to be presented were performed for exploratory endpoints including PD-L1 and gene expression profiling (GEP). An improvement in PFS for tislelizumab in combination with chemotherapy was observed regardless of PD-L1 status. GEP analysis identified a subgroup of patients who had ‘hot’ tumor immune profiles, which was characterized by the highest expression of immune cells, including T cells, natural killer cells, dendritic cells, and antigen presentation machinery. The greatest PFS benefit of tislelizumab in combination with chemotherapy was observed in patients exhibiting ‘hot’ tumor microenvironment profiles.

In August 2021, the China National Medical Products Administration (NMPA) accepted a supplemental New Drug Application (sNDA) for tislelizumab in combination with chemotherapy as a first-line treatment of adult patients with RM-NPC. BeiGene continues to support planned regulatory filings by Novartis for first-line NPC in the United States and Europe.

ASCO Plenary Series Program

Tuesday, April 19, 2022; 3 – 4 p.m. ET

This livestream event presented by ASCO will feature a presentation of abstract #384950, *"RATIONALE-309 Updated progression-free survival (PFS), PFS after next line of treatment, and overall survival from a phase 3 double-blind trial of tislelizumab versus placebo, plus chemotherapy, as first-line treatment for recurrent/metastatic nasopharyngeal cancer"* by Dr. Zhang. Participants may register for free at: https://www.asco.org/meetings-education/monthly-plenary-series/program.

About Nasopharyngeal Carcinoma

Nasopharyngeal carcinoma (NPC) is a rare cancer in which malignant cells form in the tissues of the nasopharynx and accounts for approximately 133,000 new diagnoses and 80,000 deaths per year worldwide.[1]

Recurrent or metastatic NPC exhibits a high prevalence in Southeast Asia, among other emerging markets. Known risk factors include ethnic background exposure to the Epstein-Barr virus. The prognosis for patients with recurrent or metastatic NPC treated with first-line chemotherapy remains poor, highlighting the unmet need for effective interventional therapy in the second line or later.

About RATIONALE-309

RATIONALE-309 is a multicenter, randomized, double-blind, placebo-controlled Phase 3 clinical trial (NCT03924986) designed to evaluate the efficacy and safety of tislelizumab combined with gemcitabine and cisplatin (Arm A) versus placebo combined with gemcitabine and cisplatin (Arm B) as a first-line treatment for patients with RM-NPC.

The primary endpoint of the trial is progression-free survival (PFS) in the intent-to-treat (ITT) population as assessed by an independent review committee (IRC) per RECIST v1.1 criteria; secondary endpoints include IRC-assessed overall response rate (ORR), IRC-assessed duration of response (DoR), overall survival (OS), investigator-assessed PFS, time to second objective disease progression (PFS2), and safety.

A total of 263 patients were enrolled in the trial, with 131 and 132 randomized to Arm A and Arm B, respectively, with balanced baseline characteristics between both arms. Interim results from the trial were presented in December at the European Society for Medical Oncology Immuno-Oncology (ESMO I-O) Congress. Those data showed that at a media follow-up time of 10 months, tislelizumab demonstrated a statistically significant improvement in terms of extending progression-free survival (PFS), a clinically meaningful benefit compared to chemotherapy alone on other survival endpoints, and a generally manageable safety profile.

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Tislelizumab is an anti-programmed death receptor-1 (PD-1) inhibitor designed to help aid the body's immune cells to detect and fight tumors. Tislelizumab, a humanized monoclonal antibody, is 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.

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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 plans for future development, regulatory filings and potential commercialization of tislelizumab in RM-NPC 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, manufacturing, 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.

[i] Global Cancer Observatory: Cancer Today. Lyon, France: International Agency for Research on Cancer. Available at: https://gco.iarc.fr/today/data/factsheets/cancers/4-Nasopharynx-fact-sheet.pdf. Accessed February 22, 2022

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