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 30, 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 8.01. Other Events.

On June 30, 2022, BeiGene, Ltd. ("BeiGene") announced new data from RATIONALE 306, a global Phase 3 trial evaluating tislelizumab plus chemotherapy in adult patients with advanced or metastatic esophageal squamous cell carcinoma (ESCC) without prior systemic treatment for advanced disease, presented as a late-breaking oral presentation at the 2022 European Society for Medical Oncology (ESMO) World Congress on Gastrointestinal Cancer. 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.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press release titled "BeiGene Announces Late-Breaking Data at ESMO GI Showing Overall Survival Benefit for Tislelizumab Plus Chemotherapy in First-Line Advanced or Metastatic Esophageal Squamous Cell Carcinoma" issued by BeiGene, Ltd. on June 30, 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: June 30, 2022

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

Exhibit 99.1

BeiGene Announces Late-Breaking Data at ESMO GI Showing Overall Survival Benefit for Tislelizumab Plus Chemotherapy in First-Line Advanced or Metastatic Esophageal Squamous Cell Carcinoma

- *PD-1 inhibitor tislelizumab plus chemotherapy demonstrated a statistically significant and clinically meaningful survival benefit, extending survival by more than six months compared to chemotherapy alone*

- *Incidence of most common treatment-related adverse events similar for both arms of the study, with no new safety signal identified for tislelizumab*

CAMBRIDGE, Mass. & BASEL, Switzerland & BEIJING, China – June 30, 2022 – 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 new data from RATIONALE 306, a global Phase 3 trial evaluating tislelizumab plus chemotherapy in adult patients with advanced or metastatic esophageal squamous cell carcinoma (ESCC) without prior systemic treatment for advanced disease. Study results presented today as a late-breaking oral presentation at the 2022 European Society for Medical Oncology (ESMO) World Congress on Gastrointestinal Cancer (Abstract #LBA-1) showed a statistically significant and clinically meaningful improvement in overall survival (OS) for patients receiving tislelizumab in combination with chemotherapy with a median OS of 17.2 months [95% CI: 15.8,20.1] versus 10.6 months [95% CI: 9.3,12.1] for those receiving chemotherapy plus placebo. The combination of tislelizumab with chemotherapy reduced the risk of death by 34% (HR=0.66 [95% CI: 0.54,0.80, p<0.0001]) compared to chemotherapy plus placebo.

“We are encouraged by the consistent, clinically meaningful benefit seen with tislelizumab and chemotherapy in key endpoints measuring efficacy and durability of response and across pre-specified subgroups in this 1L ESCC treatment setting,” said Mark Lanasa, M.D., Chief Medical Officer, Solid Tumors at BeiGene. “We sincerely appreciate the patients with ESCC from across the world who chose to participate in this study as we search for treatment options for this challenging condition.”

The OS benefit for tislelizumab plus chemotherapy was observed regardless of baseline PD-L1 expression. The median OS for patients with PD-L1 score ≥10% was 16.6 months [(95% CI: 15.3,24.4] in the tislelizumab plus chemotherapy group versus 10.0 months [95% CI: 8.6,13.0] for patients receiving chemotherapy plus placebo (HR=0.62; 95% CI, 0.44,0.86, p=0.0020). Analysis of patients with a PD-L1 score <10% showed a median OS of 16.7 months [95% CI: 13.0,20.1] for tislelizumab plus chemotherapy versus 10.4 months [95% CI: 9.1,13.0]; (HR=0.72 [95% CI: 0.55,0.94]) for chemotherapy plus placebo. This survival benefit was consistent across all other pre-specified subgroups, including race, region, and choice of chemotherapy.

“ESCC represents the majority of esophageal cancer worldwide, but unfortunately chemotherapy by itself provides a median survival in the range of only a year, so the survival benefit seen when tislelizumab was added to chemotherapy in our study is compelling” said Harry Yoon, MD, Associate Professor of Oncology and Chair of the Gastroesophageal Cancer Disease Group at Mayo Clinic in Rochester, Minnesota. “Additionally, it is encouraging to see a familiar safety and tolerability profile for the combination consistent with those established for chemotherapy in the community.”

Progression-free survival was significantly improved for the tislelizumab plus chemotherapy (7.3 months) group compared to chemotherapy alone (5.6 months) (HR=0.62 [95% CI: 0.52,0.75, p<0.0001]). Additional benefit in overall response (ORR) was seen with tislelizumab and chemotherapy compared to chemotherapy [ORR 63.5% vs 42.4%; p<0.0001) and the median duration of response was 7.1 months [95% CI: 6.1,8.1] for tislelizumab plus chemotherapy versus 5.7 months [95% CI: 4.4,7.1] chemotherapy alone.

The incidence of treatment-related adverse events (TRAEs) was similar in both arms; the most commonly reported TRAEs (≥ 20%) were anemia, decreased neutrophil count, decreased white blood cell count, decreased appetite, nausea and peripheral sensory neuropathy.

Tislelizumab is currently under review by the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA) for advanced or metastatic ESCC after prior chemotherapy. The EMA is also reviewing tislelizumab for advanced or metastatic non-small cell lung cancer (NSCLC) after prior chemotherapy, and in combination with chemotherapy for previously untreated advanced or metastatic NSCLC. 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 approved by the China National Medical Products Administration (NMPA) as a treatment for nine indications, including a recent approval for use in patients with locally advanced or metastatic ESCC who have disease progression or are intolerant to first-line standard chemotherapy. Tislelizumab is not approved for use outside of China.

About RATIONALE 306

RATIONALE 306 (NCT03783442) is a randomized, placebo-controlled, double-blind, global Phase 3 study to evaluate the efficacy and safety of tislelizumab in combination with chemotherapy as a first-line treatment in patients with advanced or metastatic ESCC. The primary endpoint of the trial is overall survival (OS). Secondary endpoints include progression free survival, overall response rate, duration of response per RECIST v1.1, and OS in patients with PD-L1 score ≥10%, as well as health-related quality of life measures and safety.

The trial enrolled 649 patients at research centers across Asia-Pacific, Europe, and North America. Patients were randomized 1:1 to receive either tislelizumab plus chemotherapy or placebo plus chemotherapy.

About Esophageal Squamous Cell Carcinoma

There are two main types of esophageal cancer, based on the cells where cancer develop: squamous cell carcinoma (ESCC) and adenocarcinoma (EAC). ESCC is the most common subtype of esophageal cancer, accounting for more than 85% of esophageal cancers worldwide.[i,ii] Because many patients are diagnosed with ESCC at later stages of disease, management of ESCC is challenging and the overall prognosis remains poor.[iii,iv,v]

About Tislelizumab

Tislelizumab is a humanized IgG4 anti-PD-1 monoclonal antibody specifically designed to minimize binding to Fc-gamma (Fcγ) receptors on macrophages, helping to aid the body's immune cells to detect and fight tumors. In pre-clinical studies, binding to Fcγ receptors 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. More information on the clinical trial program for tislelizumab can be found at: https://www.beigene.com/en-us/science-and-product-portfolio/pipeline

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 16,000 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 European Union, Great Britain, 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.

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 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 of its drug candidates and achieve and maintain profitability; and 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 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 Wang QL, et al. Clin Epidemiol 2018;10:717–728.

ii Huang FL, Yu SJ. Asian J Surg 2018;41:210–215.

iii American Cancer Society. What is Esophageal Cancer? Available at https://www.cancer.org/cancer/esophagus-cancer/about/what-is-cancer-of-the-esophagus.html. Accessed August 2021.

iv Codipilly DC et al. Gastrointest Endosc. 2018 Sep; 88(3): 413–426.

v Abnet CC et al. Gastroenterology. 2018 Jan; 154(2): 360–373.

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