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): August 9, 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 August 9, 2022, BeiGene, Ltd. ("BeiGene") announced that the global Phase 3 RATIONALE 301 trial with tislelizumab met its primary endpoint of non-inferior overall survival versus sorafenib as a first-line treatment in adult patients with unresectable hepatocellular carcinoma. 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 Positive Global Phase 3 Trial Results for PD-1 Inhibitor Tislelizumab in First-Line Unresectable Hepatocellular Cancer" issued by BeiGene, Ltd. on August 9, 2022
104	The cover page from this Current Report on Form 8-K, formatted in Inline XBRL

Exhibit Index

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99.1	Press release titled "BeiGene Announces Positive Global Phase 3 Trial Results for PD-1 Inhibitor Tislelizumab in First-Line Unresectable Hepatocellular Cancer" issued by BeiGene, Ltd. on August 9, 2022
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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: August 10, 2022

By: /s/ Chan Lee
Name: Chan Lee
Title: Senior Vice President, General Counsel

Exhibit 99.1

BeiGene Announces Positive Global Phase 3 Trial Results for PD-1 Inhibitor Tislelizumab in First-Line Unresectable Hepatocellular Cancer

Trial met primary endpoint of non-inferior overall survival versus sorafenib

Results mark eighth positive Phase 3 trial readout for tislelizumab across multiple cancer types and lines of therapy

Data to be submitted for presentation at upcoming medical conference

CAMBRIDGE, U.S., & BASEL, Switzerland & BEIJING – August 9, 2022 – BeiGene (NASDAQ: BGNE; HKEX: 06160; SSE: 688235), a global biotechnology company focused on developing innovative and affordable oncology medicines to improve treatment outcomes and access for patients worldwide, today announced that the global Phase 3 RATIONALE 301 trial with tislelizumab met its primary endpoint of non-inferior Overall Survival (OS) versus sorafenib as a first-line treatment in adult patients with unresectable hepatocellular carcinoma (HCC). The safety profile for tislelizumab was consistent with previous studies and no new safety signals were reported. More than 600 patients in the U.S., Europe, and Asia participated in the study.

HCC is the sixth most common type of cancer worldwide, accounting for more than 900,000 new cases in 2020[i], and despite improvements in screening, surveillance rules, and imaging, more than two-thirds of patients with HCC present with advanced disease at diagnosis[ii].

"Patients with unresectable HCC face a devastating prognosis, with a median life expectancy of one year. Currently there are few treatment options if patients cannot tolerate TKI therapy or if their condition progresses," said Mark Lanasa M.D., Ph.D., Chief Medical Officer, Solid Tumors at BeiGene. "We are encouraged by the outcome of the final analysis of RATIONALE 301 and look forward to sharing the full safety and efficacy results at an upcoming medical conference."

RATIONALE 301 (NCT03412773) is a global, Phase 3, randomized, open-label study of tislelizumab compared with sorafenib as a first-line treatment in adult patients with unresectable HCC. The primary endpoint of the study is non-inferiority of OS between the two treatment groups. The key secondary endpoint is Overall Response Rate, as assessed by Blinded Independent Review Committee (BIRC) per RECIST v1.1. Other secondary endpoints include other efficacy assessments such as Progression-Free Survival, Durability of Response, and Time to Progression per BIRC, as well as measures of health-related quality of life, and safety and tolerability.

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.

The global tislelizumab clinical development program includes more than 11,000 subjects enrolled to-date in 30 countries and regions. BeiGene has initiated or completed 22 registration-enabling clinical trials. More information on the clinical trial program for tislelizumab can be found here.

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 3,300 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.

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, 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 biotechnology company that is developing and commercializing innovative and affordable oncology medicines to improve treatment outcomes and access for far more patients worldwide. With a broad portfolio, we are expediting development of our diverse pipeline of novel therapeutics through our internal capabilities and collaborations. We are committed to radically improving access to medicines for far more patients who need them. Our growing global team of more than 8,500 colleagues spans five continents, with administrative offices in Beijing, China; Cambridge, U.S.; and Basel, Switzerland. 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 the potential for tislelizumab to treat patients with unresectable HCC, plans for development of tislelizumab in HCC, BeiGene's advancement of 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.

Investor Contact:
Kevin Mannix
+1 240-410-0129
ir@beigene.com

Media Contact:
Kathleen Cuca
+1 551 222 6790
media@beigene.com

[i] GLOBOCAN 2020
[ii] Kim DY , Han KH . Epidemiology and surveillance of hepatocellular carcinoma. Liver Cancer 1(1), 2–14 (2012)