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 23, 2024

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 April 23, 2024, BeiGene, Ltd. announced that the European Commission approved tislelizumab as a treatment for non-small cell lung cancer across three indications, including first- and second-line use. 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 Receives European Commission Approval for Tislelizumab as Treatment for Non-Small Cell Lung Cancer" issued by BeiGene, Ltd. on April 23, 2024
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 Receives European Commission Approval for Tislelizumab as Treatment for Non-Small Cell Lung Cancer" issued by BeiGene, Ltd. on April 23, 2024
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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 23, 2024

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

Exhibit 99.1

BeiGene Receives European Commission Approval for Tislelizumab as Treatment for Non-Small Cell Lung Cancer

Comprehensive development program, including three Phase 3 clinical trials, demonstrated benefit of tislelizumab for patients with treatment-naïve and relapsed NSCLC

Decision represents tislelizumab's second approval in the region

BASEL, Switzerland & BEIJING & CAMBRIDGE, Mass. -- (BUSINESS WIRE)---April 23, 2024---BeiGene, Ltd. (NASDAQ: BGNE; HKEX: 06160; SSE: 688235), a global oncology company, today announced that the European Commission (EC) has approved tislelizumab as a treatment for non-small cell lung cancer (NSCLC) across three indications, including first- and second-line use.

"Tislelizumab is foundational for BeiGene's solid tumor portfolio and has demonstrated its potential across multiple tumor types, including NSCLC, in which there remains a significant unmet need at all stages of the disease," said Mark Lanasa, M.D., Ph.D., Chief Medical Officer, Solid Tumors at BeiGene. "Today's EC authorization marks the second in the region for tislelizumab, with both NSCLC and locally advanced or metastatic esophageal squamous cell carcinoma now approved in the European Union. Second-line use in ESCC was also approved just weeks ago by the U.S. Food and Drug Administration, putting us well on our way to fulfilling our commitment to bring this innovative therapy to many more patients around the world."

The approved indications for tislelizumab are:

- In combination with carboplatin and either paclitaxel or nab-paclitaxel for the first-line treatment of adult patients with squamous NSCLC who have locally advanced NSCLC and are not candidates for surgical resection or platinum-based chemoradiation, or metastatic NSCLC.
- In combination with pemetrexed and platinum-containing chemotherapy for the first-line treatment of adult patients with non-squamous NSCLC whose tumors have PD-L1 expression on ≥50% of tumor cells with no EGFR or ALK positive mutations and who have locally advanced NSCLC and are not candidates for surgical resection or platinum-based chemoradiation, or metastatic NSCLC.
- As monotherapy for the treatment of adult patients with locally advanced or metastatic NSCLC after prior platinum-based therapy. Patients with EGFR mutant or ALK positive NSCLC should also have received targeted therapies before receiving tislelizumab.

"Non-small cell lung cancer remains one of the most common and deadly cancers in Europe, with 50% of patients diagnosed already progressed to advanced stages, making it difficult to treat," said Luis Paz-Ares, M.D., Ph.D., Head of the Medical Oncology Service at the Hospital Universitario 12 de Octubre, Madrid. "Across three Phase 3 studies, tislelizumab has been shown to improve outcomes for patients with certain types of NSCLC, providing a new option for those facing the disease."

Tislelizumab was approved for these NSCLC indications under the brand name TIZVENI®. BeiGene plans to combine the NSCLC indications with the second-line ESCC indication under the brand name TEVIMBRA®, which will launch in the first EU countries later in 2024. TEVIMBRA is approved in the U.S. and EU for advanced or metastatic ESCC after prior chemotherapy and is under review by the European Medicines Agency and the U.S. Food and Drug Administration as a first-line treatment for patients with unresectable, recurrent, locally advanced or metastatic ESCC and for first-line gastric or gastroesophageal junction cancers.

The EC approval is based on the results from three Phase 3 studies in the RATIONALE program that enrolled 1,499 patients:

- RATIONALE 307 (NCT03594747) is an open-label, randomized Phase 3 trial that enrolled 360 patients with advanced squamous NSCLC. The study met its primary endpoint, with first-line tislelizumab in combination with chemotherapy resulting in statistically significant improvement in progression free survival (PFS), as well as higher objective response rates and a manageable safety/tolerability profile, regardless of PD-L1 expression. The most common grade ≥3 treatment emergent adverse events (TEAEs) were decreased neutrophil levels, neutropenia and leukopenia. See full study results published in *JAMA Oncology*.

- RATIONALE 304 (NCT03663205) is an open-label, randomized Phase 3 trial that enrolled 334 patients with locally advanced or metastatic non-squamous NSCLC. The study met its primary endpoint, with first-line tislelizumab in combination with chemotherapy resulting in statistically significant improvement in PFS compared to chemotherapy (HR: 0.65 [95% CI: 0.47-0.91]; P=0.0054) along with higher response rates and longer response duration. The most common grade ≥3 TEAEs were associated with chemotherapy and included neutropenia and leukopenia. See full study results published in the *Journal of Thoracic Oncology*.
- RATIONALE 303 (NCT03358875) is an open-label, randomized Phase 3 trial with tislelizumab versus docetaxel that enrolled 805 patients with advanced NSCLC who progressed on prior platinum-based chemotherapy. The study met its primary endpoint, with second- or third-line tislelizumab resulting in statistically significant and clinically meaningful improvement in overall survival compared with docetaxel in the intent-to-treat population (HR: 0.66 [95% CI: 0.56-0.79]; P<0.0001), regardless of PD-L1 expression. The most commonly reported grade ≥3 TEAEs were pneumonia, anemia and dyspnea. See full study results published in the *Journal of Thoracic Oncology*.

BeiGene has launched more than 17 potentially registration-enabling trials with tislelizumab, of which 11 Phase 3 randomized trials and four Phase 2 trials have already had positive readouts. Through these trials, tislelizumab has demonstrated its potential to deliver clinically meaningful improvements in survival benefits and quality of life for hundreds of thousands of cancer patients across a range of tumor types – in many cases, regardless of PD-(L)1 status – both as monotherapy and in combination with other regimens. More than 900,000 patients have been prescribed tislelizumab globally to date.

About NSCLC
Lung cancer is the second most common type of cancer and the leading cause of cancer-related death worldwide.[1] Lung cancer is the third most common cancer in Europe; NSCLC represents 85–90% of all lung cancers.[2] In 2020, the number of new cases of lung cancer diagnosed in Europe was estimated at 477,534.[3]

About Tislelizumab
Tislelizumab is a uniquely designed humanized immunoglobulin G4 (IgG4) anti-programmed cell death protein 1 (PD-1) monoclonal antibody with high affinity and binding specificity against PD-1. It is designed to minimize binding to Fc-gamma (Fcγ) receptors on macrophages, helping to aid the body's immune cells to detect and fight tumors.

Important Safety Information
The full European Summary of Product Characteristics (SmPC) for the NSCLC indications for tislelizumab, which includes safety data for NSCLC and ESCC, is available from the European Medicines Agency.

About BeiGene
BeiGene is a global oncology company that is discovering and developing innovative oncology treatments that are more affordable and accessible to cancer 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 10,000 colleagues spans five continents, with administrative offices in Basel, Beijing, and Cambridge, U.S. To learn more about BeiGene, please visit www.beigene.com and follow us on LinkedIn, X (formerly known as Twitter), and Facebook.

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 ability to fulfill its commitment to bring tislelizumab to more patients around the world; tislelizumab's potential to deliver clinically meaningful improvements in survival benefits and quality of life for hundreds of thousands of cancer patients across a range of tumor types; and BeiGene's plans, commitments, aspirations, and goals under the heading "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, commercialization, 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 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.

Investor Contact:
Liza Heapes
+1 857-302-5663
ir@beigene.com

Media Contact:
Kyle Blankenship
+1 667-351-5176
media@beigene.com

To access BeiGene media resources, please visit our **News & Media** site.

[1] Globocan 2020. 900-world-fact-sheets.pdf (iarc.fr).
[2] European Society of Medical Oncology. What is Non-Small-Cell Lung Cancer? https://www.esmo.org/content/download/7252/143219/file/en-non-small-cell-lung-cancer-guide-for-patients.pdf.
[3] Sung H, et al. Global cancer statistics 2020: GLOBOCAN estimates of incidence and mortality worldwide for 36 cancers in 185 countries. CA Cancer J Clin. 2021;71(3):209-49.