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): March 10, 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 March 10, 2021, BeiGene, Ltd. (the "Company") announced that the first patient has been dosed in a Phase 1 clinical trial of BGB-15025, its investigational hematopoietic progenitor kinase 1 (HPK1) inhibitor. BGB-15025 is designed to be a potent and highly selective small molecule oral inhibitor of HPK1, a kinase downstream of the T cell receptor (TCR) signaling pathway that is believed to play a key role in T cell activation. 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 Initiates Phase 1 Clinical Trial for HPK1 Inhibitor BGB-15025" issued on March 10, 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 Initiates Phase 1 Clinical Trial for HPK1 Inhibitor BGB-15025" issued on March 10, 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: March 10, 2021

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

Exhibit 99.1

BeiGene Initiates Phase 1 Clinical Trial for HPK1 Inhibitor BGB-15025

CAMBRIDGE, Mass. & BEIJING — (BUSINESS WIRE)—Mar. 10, 2021-- BeiGene, Ltd. (NASDAQ: BGNE; HKEX: 06160), a commercial-stage biotechnology company focused on developing and commercializing innovative medicines worldwide, today announced that the first patient has been dosed in a Phase 1 clinical trial of BGB-15025, its investigational hematopoietic progenitor kinase 1 (HPK1) inhibitor. BGB-15025 is designed to be a potent and highly selective small molecule oral inhibitor of HPK1, a kinase downstream of the T cell receptor (TCR) signaling pathway that is believed to play a key role in T cell activation.

“We are incredibly proud of BeiGene’s research organization, which now has over 450 people, and its ability to discover not only potentially best-in-class cancer treatments but also investigational agents like BGB-15025, which we believe to be among the first HPK1 inhibitors to enter the clinic and represent a novel immuno-oncology approach targeting T cell activation to fight cancer growth,” commented Lai Wang, Ph.D., Senior Vice President, Head of Global Research, Clinical Operations & Biometrics and APAC Clinical Development at BeiGene. “We believe that the unique nature of BGB-15025 and the HPK1 pathway provides us with a compelling scientific rationale for investigating it as a monotherapy and in combination with our anti-PD-1 antibody, tislelizumab. We are excited to advance its clinical development globally.”

This first-in-human Phase 1 trial (NCT04649385) will assess the safety, tolerability, pharmacokinetics, and preliminary antitumor activity of BGB-15025 alone and in combination with tislelizumab in patients with advanced solid tumors. This trial will be conducted in multiple countries globally.

About BGB-15025

BGB-15025 is an investigational hematopoietic progenitor kinase 1 (HPK1) inhibitor discovered and being developed by BeiGene. HPK1 is a key negative feedback regulator of T-cell receptor signaling, which is believed to play a key role in antitumor immune response. In preclinical studies, the inhibition of HPK1 enhanced T-cell activation, which is expected to enhance the anti-tumor activity of anti-PD-1 inhibitors such as BeiGene’s tislelizumab.

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 approved medicine from BeiGene’s immuno-oncology biologics program and is being developed globally as a monotherapy and in combination with other therapies for the treatment of a broad array of both solid tumor and hematologic cancers.

Tislelizumab is approved in China for first-line treatment of patients with advanced squamous non-small cell lung cancer (NSCLC) in combination with chemotherapy. Tislelizumab has also received conditional approval in China 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 and are under review in China for first-line treatment of patients with advanced non-squamous NSCLC in combination with

chemotherapy, for the second- or third-line treatment of patients with locally advanced or metastatic NSCLC who progressed on prior platinum-based chemotherapy, and for previously treated unresectable hepatocellular carcinoma.

Currently, 15 potentially registration-enabling clinical trials are being conducted in China and globally, including 12 Phase 3 trials and two pivotal Phase 2 trials.

In January 2021, BeiGene and Novartis entered into a collaboration and license agreement to develop, manufacture, and commercialize tislelizumab in North America, Europe, and Japan.
Tislelizumab is not approved for use outside of China.

About BeiGene

BeiGene is a global, commercial-stage biotechnology company focused on discovering, developing, manufacturing, and commercializing innovative medicines to improve treatment outcomes and access for patients worldwide. Our 5,400+ employees around the world are committed to expediting the development of a diverse pipeline of novel therapeutics. We currently market two internally discovered oncology medicines: BTK inhibitor BRUKINSA® (zanubrutinib) in the United States and China, and anti-PD-1 antibody tislelizumab in China. We also market or plan to market in China additional oncology products licensed from Amgen Inc., Celgene Logistics Sàrl, a Bristol Myers Squibb (BMS) company, and EUSA Pharma; and have entered a collaboration with Novartis Pharma AG for Novartis to develop and commercialize tislelizumab in North America, Europe, and Japan. To learn more about BeiGene, please visit www.beigene.com and follow us on Twitter at @BeiGeneUSA.

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 future development of BGB-15025 and tislelizumab, the potential for BGB-15025 and the HPK1 pathway to play a key role in T cell activation and antitumor immune response, and the future development, regulatory approvals and commercialization of tislelizumab. 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; 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 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.

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