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 28, 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. ☐

Item 8.01. Other Events.

On April 28, 2021, BeiGene, Ltd. ("BeiGene") announced positive results from a planned interim analysis of the Phase 3 ALPINE trial comparing BRUKINSA® (zanubrutinib) against ibrutinib in adults with relapsed or refractory (R/R) chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL). ALPINE is BeiGene's second Phase 3 head-to-head trial comparing BRUKINSA to ibrutinib. 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 "BRUKINSA® (Zanubrutinib) Demonstrates Superior Objective Response Rate by Investigator Assessment and Reduced Rates of Atrial Fibrillation or Flutter at Interim Analysis in Head-to-Head Trial Against Ibrutinib in Chronic Lymphocytic Leukemia", issued by BeiGene, Ltd. on April 28, 2021.
104	The cover page from this Current Report on Form 8-K, formatted in Inline XBRL.

Exhibit Index

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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: April 28, 2021

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

Exhibit 99.1

BRUKINSA® (Zanubrutinib) Demonstrates Superior Objective Response Rate by Investigator Assessment and Reduced Rates of Atrial Fibrillation or Flutter at Interim Analysis in Head-to-Head Trial Against Ibrutinib in Chronic Lymphocytic Leukemia

CAMBRIDGE, Mass. and BEIJING, CHINA – April 28, 2021 – BeiGene (NASDAQ: BGNE; HKEX: 06160) announced positive results from a planned interim analysis of the Phase 3 ALPINE trial comparing BRUKINSA® (zanubrutinib) against ibrutinib in adults with relapsed or refractory (R/R) chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL).

BRUKINSA met the primary endpoint of the trial, demonstrating non-inferiority in objective response rate (ORR) by both investigator and independent review committee (IRC) assessments ($p < 0.0001$). The trial also demonstrated superior ORR with a statistically significant improvement in ORR for BRUKINSA vs. ibrutinib ($p = 0.0006$) by investigator assessment, as well as a numerically higher ORR but not statistically significant improvement by IRC ($p = 0.0121$ compared to the two-sided stringent statistical boundary of $p < 0.0099$ set for the interim analysis). The interim analysis from this fully-enrolled, ongoing trial is based on 415 of 652 patients followed for a minimum of 12 months.

Data pertaining to progression-free survival (PFS) in the 652 patients, a secondary endpoint of the trial, were immature at the data cutoff for the interim analysis. However, the descriptive summaries of PFS showed an early trend favoring BRUKINSA.

The trial also met a pre-specified secondary endpoint related to safety. Compared to ibrutinib, BRUKINSA demonstrated a statistically significant lower risk of atrial fibrillation or flutter, which is characterized by an irregular heartbeat that can lead to blood clots, stroke, heart failure and other heart-related complications. Overall, the safety profile of BRUKINSA was consistent with the previously seen profile in its clinical development program.

ALPINE is BeiGene's second Phase 3 head-to-head trial comparing BRUKINSA to ibrutinib.

Jane Huang, M.D., Chief Medical Officer, Hematology of BeiGene said, "The interim results from this head-to-head trial demonstrated that, as a selective inhibitor designed to deliver sustained and continuous inhibition of BTK, BRUKINSA provides CLL patients with improvements in response and reduced rates of atrial fibrillation or flutter compared to ibrutinib. Data from this interim analysis, in addition to BRUKINSA's comprehensive clinical program, provide important new information to support its benefit-risk profile."

BeiGene plans to consult with global regulatory authorities on next steps and present these data at an upcoming major medical conference. ORR per IRC will be further assessed at the planned final analysis, and patients will be followed for analyses on key secondary endpoints including PFS.

About Chronic Lymphocytic Leukemia and Small Lymphocytic Lymphoma

Chronic lymphocytic leukemia (CLL) is the most common form of leukemia in adults, with a global incidence of approximately 114,000 new cases in 2017.[1,2] CLL affects white blood cells or lymphocytes in the bone marrow.[1] Proliferation of cancer cells (leukemia) in the marrow result in reduced ability to fight infection and spread into the blood, which affects other parts of the body including the lymph nodes, liver and spleen.[1,3] The BTK pathway is a known route that signals malignant B cells and contributes to the onset of CLL.[4] Small lymphocytic lymphoma (SLL) is a non-Hodgkin's lymphoma affecting the B-lymphocytes of the immune system, which shares many similarities to CLL but with cancer cells found mostly in lymph nodes.[5]

About ALPINE

ALPINE is a randomized, global Phase 3 trial (NCT03734016) comparing BRUKINSA against ibrutinib in previously treated patients with relapsed or refractory chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL).

In the trial, a total of 652 patients were randomized into two arms with the first receiving BRUKINSA (160 mg orally twice daily) and the second receiving ibrutinib (420 mg orally once daily) until disease progression or unacceptable toxicity. The primary analysis of objective response rate (ORR), defined by pre-specified non-inferiority of BRUKINSA versus ibrutinib, was assessed by investigator and independent review committee (IRC) using the modified 2008 iwCLL guidelines with modification for treatment-related lymphocytosis for patients with CLL and per Lugano Classification for non-Hodgkin's lymphoma for patients with SLL. There was hierarchical testing of non-inferiority followed by superiority in ORR as assessed by investigator and IRC. Key secondary endpoints include progression-free survival (PFS), duration of response, overall survival, and incidence of adverse events. The study is ongoing, with pre-specified endpoints of ORR and PFS to be evaluated at the planned final analysis expected in 2022.

About BRUKINSA

BRUKINSA is a small molecule inhibitor of Bruton's tyrosine kinase (BTK) discovered by BeiGene scientists that is currently being evaluated globally in a broad clinical program as a monotherapy and in combination with other therapies to treat various B-cell malignancies. Because new BTK is continuously synthesized, BRUKINSA was specifically designed to deliver complete and sustained inhibition of the BTK protein by optimizing bioavailability, half-life, and selectivity. With differentiated pharmacokinetics compared to approved BTK inhibitors, BRUKINSA has been demonstrated to inhibit the proliferation of malignant B cells within a number of disease relevant tissues.
BRUKINSA is approved in the following indications and regions:

- For the treatment of mantle cell lymphoma (MCL) in adult patients who have received at least one prior therapy (United States, November 2019)*;
- For the treatment of MCL in adult patients who have received at least one prior therapy (China, June 2020)**;
- For the treatment of chronic lymphocytic leukemia or small lymphocytic lymphoma (CLL/SLL) in adult patients who have received at least one prior therapy (China, June 2020)**;
- For the treatment of relapsed or refractory MCL (United Arab Emirates, February 2021); and
- For the treatment of Waldenström's macroglobulinemia (WM) in adult patients (Canada, March 2021).

To-date, more than 30 marketing authorization applications in multiple indications have been submitted outside of the United States and China, covering the EU and more than 20 other countries.

*This indication was approved under accelerated approval based on overall response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.

**This indication was approved under conditional approval. Complete approval for this indication may be contingent upon results from ongoing randomized, controlled confirmatory clinical trials.

Please see the full U.S. Prescribing Information for BRUKINSA.

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 to patients across the globe. We have a growing R&D team of approximately 2,300 colleagues dedicated to advancing more than 80 clinical trials involving more than 13,000 patients. Our expansive portfolio is directed by a predominantly internalized clinical development team supporting trials in more than 40 countries. Hematology-oncology and solid tumor target therapies, and immuno-oncology are key focus areas for the Company with both mono- and combination therapies prioritized in our research and development. The Company currently markets two medicines discovered and developed in our labs: BTK inhibitor BRUKINSA in the United States, China, Canada, and additional international markets, and non-FC-gamma receptor binding anti-PD-1 antibody tislelizumab 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 and Bristol Myers Squibb. We also plan to address greater areas of unmet need globally through our collaborations including with Amgen, EUSA Pharma, Bio-Thera, SeaGen, Mirati Therapeutics, and Zymeworks. BeiGene has also entered into a collaboration with Novartis Pharma AG granting Novartis rights to develop, manufacture, and commercialize tislelizumab in North America, Europe, and Japan.

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 committed to expediting the development of our diverse pipeline of novel therapeutics through collaborations or our own internal capabilities, with the aspirational goal of radically improving access to medicines for two billion more people by 2030. BeiGene is a headquarter-less company by design, with a growing global team of approximately 6,000 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 results from the interim analysis of the Phase 3 ALPINE trial and the potential implications of these data for patients, BeiGene's plan to consult global regulatory authorities on next steps and present the data at an upcoming medical conference, the expected timing for the final analysis of the ALPINE trial, BeiGene's plan for the advancement, and anticipated clinical development, regulatory milestones and commercialization of BRUKINSA, 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 risks that final results from the ALPINE trial, including early trends in PFS, may differ from the interim results or current expectations; the interim and/or final results of the ALPINE trial will not support filings for regulatory approvals of zanubrutinib for the treatment of patients with CLL, and the timing of any such filings and potential approvals; clinical data continue to support a risk-benefit profile for BRUKINSA; 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, 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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