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): December 13, 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 December 13, 2022, BeiGene, Ltd. ("BeiGene") presented the final progression-free survival analysis of the ALPINE trial demonstrating superior efficacy and favorable cardiac safety profile for patients receiving BRUKINSA® (zanubrutinib) as compared to IMBRUVICA® (ibrutinib) in a global phase 3 trial in patients with relapsed/refractory chronic lymphocytic leukemia or small lymphocytic leukemia. The data was presented during the late-breaking session at the 64th American Society of Hematology Annual Meeting in New Orleans and simultaneously published in The New England Journal of Medicine. 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.	
99.1	Press release titled "BeiGene's BRUKINSA® (zanubrutinib) Demonstrated Superior Progression-Free Survival Over IMBRUVICA® (ibrutinib) in Chronic Lymphocytic Leukemia in Late-Breaker at ASH" issued by BeiGene, Ltd. on December 13, 2022
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: December 19, 2022

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

Exhibit 99.1

BeiGene's BRUKINSA® (zanubrutinib) Demonstrated Superior Progression-Free Survival Over IMBRUVICA® (ibrutinib) in Chronic Lymphocytic Leukemia in Late-Breaker at ASH

Final ALPINE Progression-Free Survival (PFS) results simultaneously published in The New England Journal of Medicine and presented at late-breaking session at 64th American Society of Hematology Annual Meeting

BRUKINSA demonstrated superiority to IMBRUVICA in both PFS and Overall Response Rate with fewer cardiac events

CAMBRIDGE, U.S., BASEL, Switzerland & BEIJING – December 13, 2022 – BeiGene (NASDAQ: BGNE; HKEX: 06160; SSE: 688235) a global biotechnology company, today presented the final progression-free survival (PFS) analysis of the ALPINE trial demonstrating superior efficacy and a favorable cardiac safety profile for patients receiving BRUKINSA® as compared to IMBRUVICA® in a global phase 3 trial in patients with relapsed/refractory (R/R) chronic lymphocytic leukemia (CLL) or small lymphocytic leukemia (SLL). These data will be presented (Abstract #LBA-6) during the late-breaking session at the 64th American Society of Hematology (ASH) Annual Meeting in New Orleans and simultaneously published in The New England Journal of Medicine. The paper's lead author Jennifer Brown, M.D., Ph.D., Director, CLL Center at Dana-Farber Cancer Institute will present these data.

Dr. Brown noted that "PFS is the gold standard for measuring efficacy in CLL clinical trials. The ALPINE data showing superior efficacy and consistent benefit across patient subgroups including patients with high-risk del(17p)/TP53, along with a favorable cardiovascular safety profile, provide compelling evidence for BRUKINSA as a practice-changing Bruton's tyrosine kinase (BTK) inhibitor for patients with CLL."

"BRUKINSA was specifically designed to maximize BTK occupancy and minimize off-target effects. Our clinical development programs were intended to test for a differentiated efficacy and safety profile," said Mehrdad Mobasher, M.D., M.P.H., Chief Medical Officer, Hematology at BeiGene. "We believe the ALPINE PFS data and cardiac safety results for BRUKINSA, including an absence of cardiac death, demonstrate a meaningful advance in outcomes for patients with CLL."

In this final analysis, BRUKINSA achieved superior PFS over ibrutinib (HR: 0.65 [95% CI, 0.49-0.86] p=0.0024, for both Independent Review Committee [IRC] and investigator). At 24 months, the investigator-assessed PFS rates were 78.4% for BRUKINSA compared to 65.9% with ibrutinib. The PFS benefit was observed across all major subgroups, including high-risk del(17p)/TP53 (HR: 0.52; [95% CI, 0.30-0.88]), as assessed by IRC. BRUKINSA also demonstrated higher overall response rate (ORR), with a response rate of 80.4% versus 72.9% (two-sided p=0.0264), as assessed by IRC.

BRUKINSA was generally well-tolerated with fewer adverse events leading to treatment discontinuation compared with ibrutinib (15.4% vs. 22.2%). There was a lower rate of cardiac disorders for BRUKINSA compared with ibrutinib (21.3% vs 29.6%), and cardiac disorders leading to treatment discontinuation occurred in one BRUKINSA patient versus 14 ibrutinib patients (0.3% vs. 4.3%). No patient receiving BRUKINSA died due to a cardiac adverse event; six patients receiving ibrutinib experienced a fatal cardiac adverse event (0% vs. 1.9%). The most commonly reported treatment emergent adverse events (≥20%) with BRUKINSA and ibrutinib were diarrhea (16.0% vs. 24.1%), hypertension (14.8% vs. 11.1%), neutropenia (22.8% vs. 18.2%), COVID-19 (23.1% vs. 17.9%), and upper respiratory tract infection (21.0% vs. 14.2%).

CLL is the most common type of leukemia in adults, accounting for about one-quarter of new cases of leukemia in the United States.[1] The condition is characterized by consecutive relapses, with response to therapy ultimately determining clinical benefit, including survival.

BeiGene's sNDA for BRUKINSA in CLL is currently under review with the FDA and has a target action date of January 20, 2023.

Investor Events

- **Tuesday, December 13, 2022 -** BeiGene will host a webcast and conference call following the ALPINE late-breaker presentation at 2:00 p.m. CST. BeiGene senior management along with invited medical experts will review the presented data and join for a Q&A panel.
    - Dial in: 855-303-0072; Passcode: 306575

- **Tuesday, December 13, 2022 -** BeiGene will host a webcast in Chinese at 6:00 p.m. CST/December 14, 2022 8:00 a.m. China time to capture company presentations at ASH. BeiGene senior management will review highlights of the presented data.
    - Dial in: +86 10 8783 3177 or +86 10 5387 6330; Passcode: 03233799

These events can be accessed live from the Investors section of BeiGene's website at http://ir.beigene.com, http://hkexir.beigene.com or https://sseir.beigene.com. Archived replays will be posted for 90 days following both events.

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 SLL. In the trial, a total of 652 patients across Europe (60%), the United States (17%), China (14%), New Zealand and Australia (9%) 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 endpoint of overall response rate (ORR), defined by pre-specified non-inferiority of BRUKINSA versus ibrutinib, was assessed by investigator and 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 pre-specified hierarchical testing of non-inferiority followed by superiority in ORR as assessed by investigator and IRC. Key secondary endpoints include PFS and event rate of atrial fibrillation or flutter; other secondary endpoints include duration of response, overall survival, and incidence of adverse events.

Interim study results from ALPINE were published online in Journal of Clinical Oncology in November 2022 (DOI: 10.1200/JCO.22.00510).

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. BRUKINSA was specifically designed to deliver targeted and sustained inhibition of the BTK protein by optimizing bioavailability, half-life, and selectivity. With differentiated pharmacokinetics compared to other approved BTK inhibitors, BRUKINSA has been demonstrated to inhibit the proliferation of malignant B cells within a number of disease-relevant tissues.

BRUKINSA is supported by a broad clinical program which includes more than 4,700 subjects in 35 trials in more than 30 geographies. To date, BRUKINSA is approved in more than 60 markets, including the United States, China, the European Union, Great Britain, Canada, Australia, South Korea, Switzerland, and additional international markets.

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 9,000 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 implications of the Phase 3 ALPINE trial data for patients, the timing of regulatory review and potential approval of BRUKINSA as a new treatment option for patients with CLL, the potential for BRUKINSA to provide clinical benefit to patients with CLL, 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 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, 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; 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.

IMBRUVICA® is a registered trademark of Pharmacyclics LLC and Janssen Biotech, Inc.

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References

[1] National Cancer Institute. Surveillance, Epidemiology, and End Results Program. Cancer Stat Facts: Leukemia —Chronic Lymphocytic Leukemia (CLL). Accessed October 4, 2021. https://seer.cancer.gov/statfacts/html/clyl.html