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 17, 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 August 17, 2021, BeiGene, Ltd. (“BeiGene”) and EUSA Pharma (UK), Ltd. announced that the China National Medical Products Administration (NMPA) has granted QARZIBA® (dinutuximab beta) conditional approval for the treatment of high-risk neuroblastoma in patients aged 12 months and above who have previously received induction chemotherapy and achieved at least a partial response, followed by myeloablative therapy and stem cell transplantation, as well as patients with a history of relapsed or refractory (R/R) neuroblastoma with or without residual disease. Dinutuximab beta is a targeted immunotherapy approved by the European Medicines Agency. 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 and EUSA Pharma Announce China NMPA Approval of QARZIBA® (Dinutuximab Beta) for Patients with High-Risk Neuroblastoma", issued by BeiGene, Ltd. on August 17, 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 and EUSA Pharma Announce China NMPA Approval of QARZIBA® (Dinutuximab Beta) for Patients with High-Risk Neuroblastoma", issued by BeiGene, Ltd. on August 17, 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: August 19, 2021

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

Exhibit 99.1

BeiGene and EUSA Pharma Announce China NMPA Approval of QARZIBA® (Dinutuximab Beta) for Patients with High-Risk Neuroblastoma

CAMBRIDGE, Mass., BEIJING, China, and HEMEL HEMPSTEAD, England - August 17, 2021 - BeiGene, Ltd. (NASDAQ: BGNE; HKEX: 06160) and EUSA Pharma (UK), Ltd. today announced that the China National Medical Products Administration (NMPA) has granted QARZIBA® (dinutuximab beta) conditional approval for the treatment of high-risk neuroblastoma in patients aged 12 months and above who have previously received induction chemotherapy and achieved at least a partial response, followed by myeloablative therapy and stem cell transplantation, as well as patients with a history of relapsed or refractory (R/R) neuroblastoma with or without residual disease. Dinutuximab beta is a targeted immunotherapy approved by the European Medicines Agency (EMA).[i]

"Dinutuximab beta represents an important biologic therapy for pediatric patients in China, having been listed in the first batch of New Drugs in Urgent Clinical Need Marketed Overseas by the NMPA," commented Xiaobin Wu, Ph.D., President, Chief Operating Officer, and General Manager of China at BeiGene. "For these young patients fighting neuroblastoma in China, we are proud to bring the first approved treatment."

"We are delighted that the benefit of dinutuximab beta has been recognized in China. This approval represents an important milestone in our mission and collaboration with BeiGene of bringing innovative cancer and rare disease therapies to patients," said Carsten Thiel, Ph.D., Chief Executive Officer of EUSA Pharma.

The approval of dinutuximab beta in China for the treatment of patients with high-risk neuroblastoma was supported by clinical results available from key trials conducted by SIOPEN (The International Society of Paediatric Oncology Europe Neuroblastoma Group) in collaboration with APEIRON Biologics and EUSA Pharma. These randomized controlled trials evaluated the efficacy of dinutuximab beta by comparing the administration of dinutuximab beta with and without interleukin-2 (IL-2) in the first-line treatment of patients with high-risk neuroblastoma and in two single-arm studies in the R/R setting. In the SIOPEN trial (HR-NBL1), the five-year event-free survival (EFS) rate in patients treated with dinutuximab beta was 57% vs. 42% of historical controls ($p<0.01$) and the five-year overall survival (OS) rate was 64% vs. 50% ($p\leq0.0001$).[ii] The safety of dinutuximab beta has been evaluated in 514 patients. The most common adverse reactions were pyrexia and pain that occurred despite analgesic treatment. Other frequent adverse reactions were hypersensitivity, vomiting, diarrhea, capillary leak syndrome, and hypotension.

About QARZIBA® (dinutuximab beta)

QARZIBA® is a monoclonal antibody that is specifically directed against the carbohydrate moiety of disialoganglioside 2 (GD2), which is overexpressed on neuroblastoma cells. Dinutuximab beta was approved by the European Commission in 2017 (See EMA Summary of Product Characteristics (SmPC)) and is indicated for the treatment of high-risk neuroblastoma in patients aged 12 months and above, who have previously received induction chemotherapy and achieved at least a partial response, followed by myeloablative therapy and stem cell transplantation, as well as patients with a history of relapsed or refractory neuroblastoma, with or without residual disease. Prior to the treatment of relapsed neuroblastoma, any actively progressing disease should be stabilized by other suitable measures.

About EUSA Pharma

Founded in March 2015, EUSA Pharma is a world-class biopharmaceutical company focused on oncology and rare disease. The company has extensive commercial operations in the United States and Europe, alongside a direct presence in select other markets across the globe. EUSA Pharma is led by an experienced management team with a strong record of building successful pharmaceutical companies and is supported by significant funding raised from leading life science investor EW Healthcare Partners. For more information please visit www.eusapharma.com.

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 90 clinical trials involving more than 13,000 patients and healthy volunteers. Our expansive portfolio is directed by a predominantly internalized clinical development team supporting trials in more than 40 countries. 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. The Company currently markets three 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 and 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 and Bristol Myers Squibb. We also plan to address greater areas of unmet need globally through our collaborations including with Amgen, Bio-Thera, EUSA Pharma, Mirati Therapeutics, Seagen, and Zymeworks. BeiGene has also entered into a collaboration with Novartis 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 expediting development of our diverse pipeline of novel therapeutics through our own capabilities and collaborations. We are committed to radically improving access to medicines for two billion more people by 2030. BeiGene has a growing global team of approximately 7,000 colleagues across five continents. To learn more about BeiGene, please visit www.beigene.com and follow us on Twitter at @BeiGeneGlobal

BeiGene 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 planned launch, potential benefits to patients, and opportunity of QARZIBA® in China, and other information that is not historical information. 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 products and drug candidates, if approved; BeiGene's ability to obtain and maintain protection of intellectual property for its technology and drugs; BeiGene's reliance on third parties to conduct drug development, manufacturing and other services; BeiGene’s limited operating history and BeiGene's ability to obtain additional funding for operations and to complete the development and commercialization of its drug candidates, 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.

Contacts

EUSA Media
Rebecca Kerr
+44 7909 703627
media@eusapharma.com

BeiGene Investors
Gabrielle Zhou
+86 010 5895 8058 or +1 857-302-5189
ir@beigene.com

BeiGene Media
Liza Heapes or Vivian Ni
+1 857-302-5663 or +1 857-302-7596
media@beigene.com

References

[i] European Medicines Agency, Qarziba (previously Dinutuximab beta EUSA and Dinutuximab beta APEIRON Biologics). Accessed: August 2021 via https://www.ema.europa.eu/en/medicines/human/EPAR/qarziba#authorisation-details-section

[ii] Ladenstein, R et al. *Cancers* 2020, 12, 309; doi:10.3390/cancers12020309