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): January 25, 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 January 25, 2021, EUSA Pharma (UK) Limited ("EUSA Pharma") and BeiGene, Ltd. (“BeiGene”) announced that the Biologics License Application (BLA) for SYLVANT® (siltuximab for injection) was accepted by the China National Medical Products Administration (NMPA) and granted priority review. Siltuximab is a monoclonal antibody approved by the European Medicines Agency (EMA) and the U.S. Food and Drug Administration (FDA) for the treatment of adult patients with multicentric Castleman’s disease (MCD) who are human immunodeficiency virus (HIV) negative and human herpesvirus-8 (HHV-8) negative, also known as idiopathic MCD (iMCD). iMCD is a rare, life-threatening and debilitating condition of the lymph nodes and related tissues. Siltuximab is listed in the first batch of New Drugs in Urgent Clinical Need Marketed Overseas by the NMPA. 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 "EUSA Pharma and BeiGene Announce Acceptance of a Biologics License Application for SYLVANT® (Siltuximab for Injection) in China" issued on January 25, 2021.
104	The cover page from this Current Report on Form 8-K, formatted in Inline XBRL.

Exhibit Index

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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: January 25, 2021

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

Exhibit 99.1

EUSA Pharma and BeiGene Announce Acceptance of a Biologics License Application for SYLVANT® (Siltuximab for Injection) in China

HEMEL HEMPSTEAD, England, BEIJING, China, and CAMBRIDGE, Mass. January 25, 2021 - EUSA Pharma (UK) Limited and BeiGene, Ltd. (NASDAQ: BGNE; HKEX: 06160) today announced that the Biologics License Application (BLA) for SYLVANT® (siltuximab for injection) was accepted by the China National Medical Products Administration (NMPA) and granted priority review. Siltuximab is a monoclonal antibody approved by the European Medicines Agency (EMA) and the U.S. Food and Drug Administration (FDA) for the treatment of adult patients with multicentric Castleman's disease (MCD) who are human immunodeficiency virus (HIV) negative and human herpesvirus-8 (HHV-8) negative, also known as idiopathic MCD (iMCD). iMCD is a rare, life-threatening and debilitating condition of the lymph nodes and related tissues. Siltuximab is listed in the first batch of New Drugs in Urgent Clinical Need Marketed Overseas by the NMPA.

"The BLA acceptance of siltuximab for review, an important treatment approved in more than 40 countries worldwide for iMCD, is good news for Chinese patients with this rare condition," commented Xiaobin Wu, Ph.D., General Manager of China and President of BeiGene. "We're glad to see continued progress in our collaboration with EUSA, which was built upon our shared commitment to bringing impactful therapies to patients in China and around the world."

Lee Morley, Chief Executive Officer of EUSA Pharma, said, "The BLA acceptance of siltuximab for review in China represents another exciting step in delivering therapies to patients in need worldwide. We will continue in our close collaboration with BeiGene and the NMPA to potentially bring siltuximab to iMCD patients in China."

About Siltuximab

Siltuximab is a monoclonal antibody that directly neutralises IL-6, an inflammatory cytokine detected at elevated levels in multiple inflammatory conditions. Siltuximab (SYLVANT®) is currently approved by the US Food and Drug Administration (FDA) and the European Commission (EC), as well as regulatory authorities in several other jurisdictions worldwide, for the treatment of adult patients with Multicentric Castleman Disease (MCD) who are human immunodeficiency virus (HIV) negative and human herpesvirus-8 (HHV-8) negative. **Indications and Usage** – See EMA Summary of Product Characteristics (SmPC) and FDA Prescribing Information for additional information.

About EUSA Pharma

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

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 5,200+ employees in China, the United States, Australia, Europe, and elsewhere are committed to expediting the development of a diverse pipeline of novel therapeutics. We currently market two internally discovered oncology products: 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. To learn more about BeiGene, please visit www.beigene.com and follow us on Twitter at @BeiGeneUSA.

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 potential approval, launch and opportunity of SYLVANT® in China, future development and potential commercialization activities of the products under the agreement with EUSA, 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.

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