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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549**

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**Form 8-K**

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**CURRENT REPORT**

**Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**

Date of Report (Date of earliest event Reported): June 21, 2022

**BEIGENE, LTD.**

**(Exact Name of Registrant as Specified in Charter)**

<b>Cayman Islands</b> (State or Other Jurisdiction of Incorporation)	<b>001-37686</b> (Commission File Number)	<b>98-1209416</b> (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)		
<b>+1 (345) 949-4123</b> (Registrant's telephone number, including area code)		
<b>Not Applicable</b> (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:

<u>Title of each class</u>	<u>Trading Symbol(s)</u>	<u>Name of each exchange on which registered</u>
<b>American Depositary Shares, each representing 13 Ordinary Shares, par value \$0.0001 per share</b>	<b>BGNE</b>	<b>The NASDAQ Global Select Market</b>
<b>Ordinary Shares, par value \$0.0001 per share*</b>	<b>06160</b>	<b>The Stock Exchange of Hong Kong Limited</b>

\*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.

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**Item 5.02 Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.**

*Director Resignation*

On June 22, 2022, Timothy Chen resigned from the Board of Directors (the “Board”) of BeiGene, Ltd. (the “Company”). In connection with his resignation, Mr. Chen also resigned from the Compensation Committee and the Commercial and Medical Affairs Advisory Committee of the Board. Mr. Chen served as a member of the Board since 2016. Mr. Chen resigned from the Board to devote more time to his other commitments. The decision by Mr. Chen to resign was not the result of any disagreement with respect to the operations, policies, or practices of the Company.

In connection with his resignation, Mr. Chen ceased to be an eligible participant under the Second Amended and Restated 2016 Share Option and Incentive Plan (as amended, the “2016 Plan”). The Company did not grant restricted share units to Mr. Chen under the 2016 Plan pursuant to Proposal 15 of the 2022 Annual General Meeting of Shareholders of the Company (the “Annual Meeting”), which was approved by the shareholders on June 22, 2022.

*Amendment No. 2 to the Second Amended and Restated 2016 Share Option and Incentive Plan*

On June 22, 2022, at the Annual Meeting, the Company’s shareholders approved Amendment No. 2 (“Amendment No. 2”) to the 2016 Plan to increase the number of authorized shares available for issuance under the 2016 Plan. Amendment No. 2 increases the aggregate number of shares authorized for issuance under the 2016 Plan by 66,300,000 ordinary shares, or 5.0% of the Company’s outstanding shares as of March 31, 2022, from 217,023,772 ordinary shares (of which 48,054,590 shares were reserved and remained available for issuance as of March 31, 2022) to 283,323,772 ordinary shares.

Additional information about Amendment No. 2 is included in the Company’s definitive proxy statement for the Annual Meeting filed with the Securities and Exchange Commission on April 29, 2022 (the “Proxy Statement”). In addition, the foregoing description of Amendment No. 2 is qualified by reference to Amendment No. 2, a copy of which is filed hereto as Exhibit 10.1 and is incorporated herein by reference.

*Termination of the Amended and Restated 2018 Inducement Equity Plan*

Upon the effectiveness of Amendment No. 2, the Amended and Restated 2018 Inducement Equity Plan was terminated to the effect that no new equity awards will be granted under such plan but the outstanding equity awards under such plan will continue to vest and/or be exercisable.

**Item 5.07. Submission of Matters to a Vote of Security Holders.**

On June 22, 2022, the Company held its Annual Meeting. As disclosed in the Proxy Statement, there were 1,334,805,269 ordinary shares entitled to vote at the Annual Meeting as of the record date of April 18, 2022 (the “Record Date”), of which approximately 962,669,760 were held in the name of Citibank, N.A., which issues Company-sponsored American Depositary Receipts evidencing American Depositary Shares (“ADSs”), which, in turn, each represent 13 ordinary shares, and 115,055,260 were our ordinary shares listed on the STAR Market and traded in RMB (“RMB shares”).

At the Annual Meeting, of the ordinary shares entitled to vote, 1,068,007,266 ordinary shares, including ordinary shares represented by ADSs, or approximately 80.0% of the outstanding ordinary shares on the Record Date, were present and voted in person or by proxy (including abstentions) for Resolutions 1 to 9 and 11 to 18; and 1,062,583,266 ordinary shares, including ordinary shares represented by ADSs, or approximately 79.6% of the outstanding ordinary shares on the Record Date, were present and voted in person or by proxy (including abstentions) for Resolution 10. In accordance with the Company’s Sixth Amended and Restated Memorandum and Articles of Association, the quorum required for a general meeting of shareholders at which an ordinary resolution is proposed consists of such shareholders present in person or by proxy who together hold shares carrying the right to at least a simple majority of all votes capable of being exercised on a poll.

The matters set forth below were voted on by the Company’s shareholders as of the Record Date at the Annual Meeting. Detailed descriptions of these matters and the voting procedures applicable to these matters at the Annual Meeting are contained in the Proxy Statement. Set forth below are the total number of shares voted for and against each matter, as well as the total number of abstentions and broker non-votes with respect to each matter.

(1) Ordinary resolution: to re-elect Anthony C. Hooper to serve as a Class III director until the 2025 annual general meeting of shareholders and until his successor is duly elected and qualified, subject to his earlier resignation or removal:

<u>Votes For</u>	<u>Votes Against</u>	<u>Abstentions</u>	<u>Broker Non-Votes</u>
1,006,706,801	61,091,519	208,946	—

Accordingly, Anthony C. Hooper was re-elected to serve as a Class III director.

(2) Ordinary resolution: to re-elect Ranjeev Krishana to serve as a Class III director until the 2025 annual general meeting of shareholders and until his successor is duly elected and qualified, subject to his earlier resignation or removal:

<b>Votes For</b>	<b>Votes Against</b>	<b>Abstentions</b>	<b>Broker Non-Votes</b>
943,936,889	123,966,142	104,235	—

Accordingly, Ranjeev Krishana was re-elected to serve as a Class III director.

(3) Ordinary resolution: to re-elect Xiaodong Wang to serve as a Class III director until the 2025 annual general meeting of shareholders and until his successor is duly elected and qualified, subject to his earlier resignation or removal:

<b>Votes For</b>	<b>Votes Against</b>	<b>Abstentions</b>	<b>Broker Non-Votes</b>
1,062,374,118	5,528,208	104,940	—

Accordingly, Xiaodong Wang was re-elected to serve as a Class III director.

(4) Ordinary resolution: to re-elect Qingqing Yi to serve as a Class III director until the 2025 annual general meeting of shareholders and until his successor is duly elected and qualified, subject to his earlier resignation or removal:

<b>Votes For</b>	<b>Votes Against</b>	<b>Abstentions</b>	<b>Broker Non-Votes</b>
938,217,422	129,688,844	101,000	—

Accordingly, Qingqing Yi was re-elected to serve as a Class III director.

(5) Ordinary resolution: to re-elect Margaret Dugan to serve as a Class I director until the 2023 annual general meeting of shareholders and until her successor is duly elected and qualified, subject to her earlier resignation or removal:

<b>Votes For</b>	<b>Votes Against</b>	<b>Abstentions</b>	<b>Broker Non-Votes</b>
1,067,488,510	423,504	99,252	—

Accordingly, Margaret Dugan was re-elected to serve as a Class I director.

(6) Ordinary resolution: to re-elect Alessandro Riva to serve as a Class I director until the 2023 annual general meeting of shareholders and until his successor is duly elected and qualified, subject to his earlier resignation or removal:

<b>Votes For</b>	<b>Votes Against</b>	<b>Abstentions</b>	<b>Broker Non-Votes</b>
1,064,824,026	3,079,024	104,216	—

Accordingly, Alessandro Riva was re-elected to serve as a Class I director.

The proposals for the election of directors related solely to the election of Class I and Class III directors nominated by the Board. The terms of the following directors continued after the Annual Meeting: John V. Oyler, Donald W. Glazer, Michael Goller, Thomas Malley and Corazon (Corsee) D. Sanders.

(7) Ordinary resolution: to approve and ratify the selection of Ernst & Young LLP, Ernst & Young Hua Ming LLP and Ernst & Young as the Company's reporting accounting firms for the fiscal year ending December 31, 2022:

<b>Votes For</b>	<b>Votes Against</b>	<b>Abstentions</b>	<b>Broker Non-Votes</b>
1,064,092,884	3,879,388	34,994	—

Accordingly, the selection of Ernst & Young LLP, Ernst & Young Hua Ming LLP and Ernst & Young as the Company's reporting accounting firms was approved and ratified.

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(8) Ordinary resolution: within the parameters of the Rules Governing the Listing of Securities on the Stock Exchange of Hong Kong Limited, to approve the granting of a share issue mandate to the Board to issue, allot or deal with (i) unissued ordinary shares (excluding RMB shares) and/or ADSs not exceeding 20% of the total number of issued ordinary shares (excluding RMB shares) of the Company and/or (ii) unissued RMB shares not exceeding 20% of the total number of issued RMB shares of the Company, each as of the date of passing of such ordinary resolution up to the next annual general meeting of shareholders of the Company, subject to the conditions described in the Proxy Statement (the “General Mandate to Issue Shares”):

<b>Votes For</b>	<b>Votes Against</b>	<b>Abstentions</b>	<b>Broker Non-Votes</b>
827,192,929	240,772,355	41,982	—

Accordingly, the General Mandate to Issue Shares was approved.

(9) Ordinary resolution: within the parameters of the Rules Governing the Listing of Securities on the Stock Exchange of Hong Kong Limited, to approve the granting of a share repurchase mandate to the Board to repurchase an amount of ordinary shares (excluding RMB shares) and/or ADSs, not exceeding 10% of the total number of issued ordinary shares (excluding RMB shares) of the Company as of the date of passing of such ordinary resolution up to the next annual general meeting of shareholders of the Company, subject to the conditions described in the Proxy Statement (the “General Mandate to Repurchase Shares”):

<b>Votes For</b>	<b>Votes Against</b>	<b>Abstentions</b>	<b>Broker Non-Votes</b>
1,067,051,779	919,603	35,884	—

Accordingly, the General Mandate to Repurchase Shares was approved.

(10) Ordinary resolution: to authorize the Company and its underwriters, in their sole discretion, to allocate to each of Baker Bros. Advisors LP and Hillhouse Capital Management, Ltd. and parties affiliated with each of them (the “Existing Shareholders”), up to a maximum amount of shares in order to maintain the same shareholding percentage of each of the Existing Shareholders (based on the then-outstanding share capital of the Company) before and after the allocation of the corresponding securities issued pursuant to an offering conducted pursuant to the general mandate set forth above for a period of five years, which period will be subject to an extension on a rolling basis each year (the “Connected Person Placing Authorization I”):

<b>Votes For</b>	<b>Votes Against</b>	<b>Abstentions</b>	<b>Broker Non-Votes</b>
433,605,379	351,829,256	277,148,631	—

Accordingly, the Connected Person Placing Authorization I was approved.

(11) Ordinary resolution: to authorize the Company and its underwriters, in their sole discretion, to allocate to Amgen Inc. (“Amgen”) up to a maximum amount of shares in order to maintain the same shareholding percentage of Amgen (based on the then-outstanding share capital of the Company) before and after the allocation of the corresponding securities issued pursuant to an offering conducted pursuant to the general mandate set forth above for a period of five years, which period will be subject to an extension on a rolling basis each year, conditional on the approval of the shareholders who are not Amgen (the “Connected Person Placing Authorization II”):

<b>Votes For</b>	<b>Votes Against</b>	<b>Abstentions</b>	<b>Broker Non-Votes</b>
502,813,936	326,447,520	238,745,810	—

Accordingly, the Connected Person Placing Authorization II was approved.

(12) Ordinary resolution: to approve the grant of an option to acquire shares to Amgen to allow Amgen to subscribe for additional shares under a specific mandate in an amount necessary to enable it to increase (and subsequently maintain) its ownership at approximately 20.6% of the Company’s outstanding share capital, up to an aggregate of 75,000,000 ordinary shares during the option term, pursuant to the terms of the Restated Amendment No. 2 dated September 24, 2020 (the “Restated Second Amendment”) to the Share Purchase Agreement dated October 31, 2019, as amended, by and between the Company and Amgen:

<b>Votes For</b>	<b>Votes Against</b>	<b>Abstentions</b>	<b>Broker Non-Votes</b>
707,625,627	121,690,604	238,691,035	—

Accordingly, the grant of an option to acquire shares to Amgen pursuant to the terms of the Restated Second Amendment was approved.

(13) Ordinary resolution: to approve the grant of restricted share units (“RSUs”) with a grant date fair value of US\$4,000,000 to Mr. John V. Oyler under the 2016 Plan, according to the terms and conditions described in the Proxy Statement;

<b>Votes For</b>	<b>Votes Against</b>	<b>Abstentions</b>	<b>Broker Non-Votes</b>
1,003,123,273	13,310,960	51,573,033	—

Accordingly, the grant of RSUs to Mr. John V. Oyler under the 2016 Plan was approved.

(14) Ordinary resolution: to approve the grant of RSUs with a grant date fair value of US\$1,000,000 to Dr. Xiaodong Wang under the 2016 Plan, according to the terms and conditions described in the Proxy Statement:

<b>Votes For</b>	<b>Votes Against</b>	<b>Abstentions</b>	<b>Broker Non-Votes</b>
948,040,399	105,798,613	14,168,254	—

Accordingly, the grant of RSUs to Dr. Xiaodong Wang under the 2016 Plan was approved.

(15) Ordinary resolution: to approve the grant of RSUs with a grant date fair value of US\$200,000 to each of other non-executive and independent non-executive directors, Mr. Anthony C. Hooper, Mr. Timothy Chen, Dr. Margaret Dugan, Mr. Donald W. Glazer, Mr. Michael Goller, Mr. Ranjeev Krishana, Mr. Thomas Malley, Dr. Alessandro Riva, Dr. Corazon (Corsee) D. Sanders, and Mr. Qingqing Yi, under the 2016 Plan, according to the terms and conditions described in the Proxy Statement:

<b>Votes For</b>	<b>Votes Against</b>	<b>Abstentions</b>	<b>Broker Non-Votes</b>
959,224,652	105,770,960	3,011,654	—

Accordingly, the grant of RSUs to each of the non-executive and independent non-executive directors, Mr. Anthony C. Hooper, Mr. Timothy Chen, Dr. Margaret Dugan, Mr. Donald W. Glazer, Mr. Michael Goller, Mr. Ranjeev Krishana, Mr. Thomas Malley, Dr. Alessandro Riva, Dr. Corazon (Corsee) D. Sanders, and Mr. Qingqing Yi, under the 2016 Plan, was approved.

(16) Ordinary resolution: to approve Amendment No. 2 to the Second Amended and Restated 2016 Share Option and Incentive Plan to increase the number of authorized shares available for issuance by 66,300,000 ordinary shares, subject to the conditions that the number of ordinary shares that may be issued under new options granted under the 2016 Plan and the Amended and Restated 2018 Inducement Equity Plan shall not exceed 10% of the issued share capital as of the date of the shareholders’ resolution approving Amendment No. 2 to the 2016 Plan, and such approved increase in number of authorized shares available for issuance shall be reduced to the extent necessary such that the 10% limit is not exceeded:

<b>Votes For</b>	<b>Votes Against</b>	<b>Abstentions</b>	<b>Broker Non-Votes</b>
950,481,503	117,217,711	308,052	—

Accordingly, Amendment No. 2 to the 2016 Plan was approved.

(17) Ordinary resolution: non-binding, advisory vote on the compensation of the Company’s named executive officers, as disclosed in the Proxy Statement:

<b>Votes For</b>	<b>Votes Against</b>	<b>Abstentions</b>	<b>Broker Non-Votes</b>
944,622,627	123,002,095	382,544	—

Accordingly, on a non-binding, advisory basis, the compensation of the Company’s named executive officers, as disclosed in the Proxy Statement, was approved.

(18) Ordinary resolution: to approve the adjournment of the Annual Meeting by the chairman, if necessary, to solicit additional proxies if there are insufficient votes at the time of the Annual Meeting to approve any of the proposed resolutions 1 to 17:

<b>Votes For</b>	<b>Votes Against</b>	<b>Abstentions</b>	<b>Broker Non-Votes</b>
920,563,014	147,345,244	99,008	—

Accordingly, the adjournment of the Annual Meeting by the chairman, if necessary, to solicit additional proxies if there are insufficient votes at the time of the Annual Meeting, to approve any of the proposed resolutions 1 to 17, was approved.

**Item 8.01. Other Events.**

On June 21, 2022, the Company announced that the Center for Drug Evaluation (CDE) of the China National Medical Products Administration (NMPA) accepted a supplemental biologics license application (sBLA) for the company's anti-PD-1 inhibitor, tislelizumab, in combination with chemotherapy as a first-line treatment for patients with advanced or metastatic gastric or gastroesophageal junction adenocarcinoma whose tumors express PD-L1. 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.**

<b>Exhibit No.</b>	<b>Description</b>
10.1	Amendment No. 2 to the Second Amended and Restated 2019 Share Option and Incentive Plan
99.1	Press release titled "BeiGene Announces Acceptance of Supplemental Biologics License Application in China for Anti-PD-1 Inhibitor Tislelizumab" issued by BeiGene, Ltd. on June 21, 2022
104	The cover page from this Current Report on Form 8-K, formatted in Inline XBRL

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## Exhibit Index

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<b>Exhibit No.</b>	<b>Description</b>
10.1	<a href="#">Amendment No. 2 to the Second Amended and Restated 2019 Share Option and Incentive Plan</a>
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104	The cover page from this Current Report on Form 8-K, formatted in Inline XBRL

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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: June 22, 2022

By: /s/ Scott A. Samuels

Name: Scott A. Samuels

Title: Senior Vice President, General Counsel

**AMENDMENT NO. 2  
TO  
BEIGENE, LTD. SECOND AMENDED AND RESTATED  
2016 SHARE OPTION AND EQUITY PLAN**

This Amendment No. 2 (“Amendment No. 2”) to the BeiGene, Ltd. Second Amended and Restated 2016 Share Option and Equity Plan (the “Plan”) is effective as of the date this Amendment No. 2 is approved by the shareholders of BeiGene, Ltd., a Cayman Islands exempted company incorporated with limited liability (the “Company”), as specified below.

Section 3(a) of the Plan is hereby deleted in its entirety and replaced with the following:

“(a) Shares Issuable. The maximum number of Shares that have been reserved and available for issuance under the Plan shall be 283,323,772 Shares, of which 114,354,590 Shares are reserved and remain available for issuance (representing approximately 8.6% (or less) of the issued share capital of the Company as of June 22, 2022, being the effective date of the approval of Amendment No. 2 to the second amended and restated Plan by the shareholders (the “Amended Effective Date”). For purposes of this limitation, the Shares underlying any awards granted under this Plan or the Company’s 2011 Option Plan (including any grants made prior to the Amended Effective Date) that are forfeited, canceled, held back upon exercise of an Option or settlement of an award to cover the exercise price or tax withholding, reacquired by the Company prior to vesting, satisfied without the issuance of Shares or otherwise terminated (other than by exercise) shall be added back to the Shares available for issuance under the Plan, provided that (i) the Shares reserved and available for issuance under the Plan and the Company’s 2018 Inducement Equity Plan (as amended and restated) shall not exceed 133,480,526 Shares as of the Amended Effective Date, being 10% of the issued share capital of the Company as of the Amended Effective Date, (ii) if the Company cancels an Option and issues a new Option to the same Grantee, the issue of such new Option shall be made only to the extent that Shares are reserved and available for issuance excluding the cancelled Option and (iii) notwithstanding the foregoing, no Shares underlying any Options granted under this Plan or the Company’s 2011 Option Plan (including any grants made prior to the Amended Effective Date) shall be added back to the Shares available for issuance under the Plan unless such Options have lapsed or otherwise been terminated in accordance with the terms of the Plan or the 2011 Option Plan. In the event the Company repurchases Shares on the open market, such Shares shall not be added to the Shares available for issuance under the Plan. Subject to such overall limitations, Shares may be issued up to such maximum number pursuant to any type or types of Award. The Shares available for issuance under the Plan may be authorized but unissued Shares or Shares reacquired by the Company.”

Except as provided above, the Plan shall remain in full force and effect without modification.

DATE APPROVED BY BOARD OF DIRECTORS: April 17, 2022

DATE APPROVED BY SHAREHOLDERS: June 22, 2022

**BeiGene Announces Acceptance of Supplemental Biologics License Application in China for Anti-PD-1 Inhibitor Tislelizumab**

- *Submission seeks marketing authorization for use with chemotherapy as first-line treatment in patients with advanced gastric or gastroesophageal junction adenocarcinoma whose tumor expresses PD-L1*

**CAMBRIDGE, Mass., & BASEL, Switzerland & BEIJING, China – June 21, 2022** – BeiGene (NASDAQ: BGNE; HKEX: 06160; SSE: 688235), a global, science-driven biotechnology company focused on developing innovative and affordable medicines to improve treatment outcomes and access for patients worldwide, today announced that the Center for Drug Evaluation (CDE) of the China National Medical Products Administration (NMPA) has accepted a supplemental biologics license application (sBLA) for the company’s anti-PD-1 inhibitor, tislelizumab, in combination with chemotherapy as a first-line treatment for patients with advanced or metastatic gastric or gastroesophageal junction adenocarcinoma whose tumors express PD-L1.

The sBLA is supported by data from an interim analysis from the global RATIONALE 305 trial of tislelizumab versus placebo in combination with chemotherapy as a first-line treatment for patients with locally advanced, unresectable or metastatic gastric or gastroesophageal junction (G/GEJ) adenocarcinoma. In China, gastric cancer (GC) has become the third most common cancer<sup>1</sup> and adenocarcinoma represents the major histologic subtype of GC, over 90% of reported cases across the world<sup>2</sup>.

Lai Wang, Ph.D., Global Head of R&D at BeiGene said, “Gastric cancer is the second leading cause of cancer-related deaths in China and there are few options to treat metastatic disease. We are pleased that our rigorous clinical development program has demonstrated a survival benefit with tislelizumab and chemotherapy treatment in patients whose tumors express PD-L1 and look forward to working with regulators to bring forward this potential new treatment option.”

Tislelizumab is currently under review by the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA) for advanced or metastatic ESCC after prior chemotherapy. The EMA is also reviewing tislelizumab for advanced or metastatic non-small cell lung cancer (NSCLC) after prior chemotherapy, and in combination with chemotherapy for previously untreated advanced or metastatic NSCLC. In January 2021, BeiGene announced a collaboration with Novartis to accelerate the clinical development and marketing of tislelizumab in North America, Europe, and Japan. Tislelizumab is approved by the China National Medical Products Administration (NMPA) as a treatment for nine indications and this sBLA is the 10th regulatory submission for tislelizumab in China. Tislelizumab is not approved for use outside of China.

**About RATIONALE 305 (NCT0377657)**

RATIONALE 305 is a randomized, double-blind, placebo-controlled, global Phase 3 trial comparing the efficacy and safety of tislelizumab combined with platinum and fluoropyrimidine chemotherapy and placebo combined with platinum and fluoropyrimidine chemotherapy as a first-line treatment for patients with locally advanced, unresectable or metastatic G/GEJ adenocarcinoma. The primary endpoint of the trial is overall survival (OS). Secondary endpoints include progression-free survival (PFS), overall response rate (ORR), duration of response (DoR), and safety. A total of 997 patients from 13 countries and regions across the world were enrolled and randomized 1:1 to receive either tislelizumab and chemotherapy or placebo and chemotherapy.

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## **About Tislelizumab**

Tislelizumab is a humanized IgG4 anti-PD-1 monoclonal antibody specifically designed to minimize binding to Fc-gamma (Fc $\gamma$ ) receptors on macrophages, helping to aid the body's immune cells to detect and fight tumors. In pre-clinical studies, binding to Fc $\gamma$  receptors 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 drug from BeiGene's immuno-oncology biologics program and is being developed internationally as a monotherapy and in combination with other therapies for the treatment of a broad array of both solid tumor and hematologic cancers. In January 2021, BeiGene announced a collaboration with Novartis to accelerate the clinical development and marketing of tislelizumab in North America, Europe, and Japan.

BeiGene has initiated or completed more than 20 potentially registration-enabling clinical trials in 35 countries and regions, including 17 Phase 3 trials and four pivotal Phase 2 trials. More information on the clinical trial program for tislelizumab can be found at: <https://www.beigene.com/en-us/science-and-product-portfolio/pipeline>

## **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 for patients across the globe. We have a growing R&D and medical affairs team of approximately 2,900 colleagues dedicated to advancing more than 100 clinical trials that have involved more than 16,000 subjects. Our expansive portfolio is directed predominantly by our internal colleagues supporting clinical trials in more than 45 countries and regions. 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. BeiGene currently has three approved medicines discovered and developed in our own labs: BTK inhibitor BRUKINSA® in the U.S., China, the European Union, Great Britain, Canada, Australia, and additional international markets; and the non-Fc-gamma receptor binding anti-PD-1 antibody tislelizumab as well as the 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, Bristol Myers Squibb, EUSA Pharma and Bio-Thera. We also plan to address greater areas of unmet need globally through our other collaborations including with Mirati Therapeutics, Seagen, and Zymeworks.

In January 2021, BeiGene and Novartis announced a collaboration granting Novartis rights to co-develop, manufacture, and commercialize BeiGene's anti-PD1 antibody, tislelizumab, in North America, Europe, and Japan. Building upon this productive collaboration, including a biologics license application (BLA) under U.S. Food and Drug Administration (FDA) review, BeiGene and Novartis announced an option, collaboration, and license agreement in December 2021 for BeiGene's TIGIT inhibitor, ociperlimab, that is in Phase 3 development. Novartis and BeiGene also entered into a strategic commercial agreement through which BeiGene will promote five approved Novartis Oncology products across designated regions of China.

## **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 over 8,000 colleagues across five continents. To learn more about BeiGene, please visit [www.beigene.com](http://www.beigene.com) and follow us on Twitter at [@BeiGeneGlobal](https://twitter.com/BeiGeneGlobal).

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## **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 clinical benefits and advantages of tislelizumab, BeiGene's plans for the advancement, and anticipated clinical development, regulatory milestones and commercialization of tislelizumab, the potential patient benefits, and BeiGene's plans, commitments, aspirations and goals under the captions "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 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; 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.

<sup>i</sup> Zheng R, Zhang S, Zeng H, et al. Cancer incidence and mortality in China, 2016[J]. Journal of the National Cancer Center, 2022.

<sup>ii</sup> Zheng X, Xie Y. Current status of advanced gastric cancer treatment in China. Oncology Progress, Jan 2019, Vol. 17, No. 1.

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