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 11, 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 April 11, 2021, BeiGene, Ltd. (the "Company") announced that clinical data on its anti-PD-1 antibody tislelizumab, in combination with the investigational spectrum-selective kinase inhibitor sitravatinib being jointly developed with Mirati Therapeutics, Inc. (Mirati), were presented in two oral presentations at the American Association for Cancer Research (AACR) Annual Meeting 2021. Data presented at the meeting were from two cohorts of a Phase 1b trial (NCT03666143), in patients with unresectable or metastatic melanoma who were refractory or resistant to PD-1/L1 inhibitors and in patients with advanced platinum-resistant ovarian cancer (PROC). 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.

On April 12, 2021, the Company announced results from a planned interim analysis of the Phase 3 RATIONALE 303 trial of its anti-PD-1 antibody tislelizumab compared to docetaxel as second- or third-line therapy for patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) in an oral presentation at the AACR Annual Meeting 2021. A supplemental biologics application (sBLA) based on these results from the RATIONALE 303 trial was accepted in March 2021 and is currently under regulatory review in China. The full text of this press release is filed as Exhibit 99.2 to this Current Report on Form 8-K and is incorporated herein by reference.

9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release titled "BeiGene Presents Clinical Data on Sitravatinib in Combination with Tislelizumab at the AACR Annual Meeting 2021" issued on April 11, 2021.
99.2	Press Release titled "BeiGene Presents Interim Analysis Results of RATIONALE 303 Trial of Tislelizumab in Second- or Third-Line Non-Small Cell Lung Cancer at the AACR Annual Meeting 2021" issued on April 12, 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: April 12, 2021

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

Exhibit 99.1

BeiGene Presents Clinical Data on Sitravatinib in Combination with Tislelizumab at the AACR Annual Meeting 2021

The combination showed preliminary antitumor activity in patients with unresectable or metastatic melanoma refractory or resistant to PD-1/L1 inhibitors and platinum-resistant ovarian cancer in an ongoing Phase 1b clinical trial, with a generally well-tolerated safety profile.

CAMBRIDGE, Mass. and BEIJING, China, April 11, 2021 -- BeiGene, Ltd. (NASDAQ: BGNE; HKEX: 06160), a commercial-stage biotechnology company focused on developing and commercializing innovative medicines worldwide, today announced that clinical data on its anti-PD-1 antibody tislelizumab, in combination with the investigational spectrum-selective kinase inhibitor sitravatinib being jointly developed with Mirati Therapeutics, Inc. (Mirati), were presented in two oral presentations at the American Association for Cancer Research (AACR) Annual Meeting 2021. Data presented at the meeting were from two cohorts of a Phase 1b trial (NCT03666143), in patients with unresectable or metastatic melanoma who were refractory or resistant to PD-1/L1 inhibitors and in patients with advanced platinum-resistant ovarian cancer (PROC).

BeiGene has an exclusive collaboration and license agreement with Mirati for the development, manufacturing and commercialization of sitravatinib in Asia (excluding Japan), Australia, and New Zealand.

“From the results presented today, we believe that sitravatinib in combination with tislelizumab could potentially provide clinical benefit to patients with advanced solid tumors, which supports our plan to further evaluate this innovative combination in our ongoing clinical trials. In addition, we are excited about the preliminary antitumor activity observed in patients with PD-1/L1 resistant or refractory melanoma,” commented Yong (Ben) Ben, M.D., Chief Medical Officer, Immuno-Oncology at BeiGene. “As we continue to follow these patients and complete enrollment in this trial, we are excited to expand our knowledge of this novel combination in the hope that it will lead to a combination therapy that can help more patients around the world in the fight against cancer.”

This open-label, multicohort, Phase 1b trial was designed to evaluate safety/tolerability and preliminary antitumor activity of sitravatinib in combination with tislelizumab in advanced solid tumors. The primary endpoint of the trial was safety/tolerability of the combination; key secondary endpoints include investigator-assessed objective response rate (ORR), disease control rate (DCR), and progression-free survival (PFS) per RECIST v1.1; overall survival (OS) was also assessed.

Results in Patients with Unresectable or Metastatic Melanoma Refractory or Resistant to PD-1/L1 Inhibitors

“Checkpoint inhibitors have changed the treatment of advanced melanoma, but a significant proportion of patients do not benefit from PD-1 inhibitors due to primary or innate resistance. In this Phase 1b trial, we’re glad to see that the combination of sitravatinib and tislelizumab was generally well-tolerated and demonstrated encouraging preliminary antitumor activity in patients with PD-1/L1 resistant melanoma,” commented Chuanliang Cui, Professor at Beijing Cancer Hospital in China.

At the time of data cutoff on October 13, 2020, a total of 25 patients with unresectable or metastatic melanoma who were refractory or resistant to anti-PD-1/L1 antibodies and had not received other prior immunotherapy had been enrolled in cohort G of the Phase 1b trial, including 12 with cutaneous subtype, seven with acral subtype, and four with mucosal subtype. At the time of data cutoff, 16 patients (64%) remained on study treatment. With a median follow-up time of 5.5 months, results included:

- All 25 patients (100%) experienced at least one treatment-emergent adverse event (TEAE) of any grade, with the most common (≥20%) being increased alanine transaminase (ALT; 76%), increased aspartate aminotransferase (AST; 68%), increased blood cholesterol (56%), hypertriglyceridemia (52%), hypothyroidism (48%), weight decreased (48%), increased blood creatine kinase (BCK; 40%), diarrhea (40%), increased gamma-glutamyltransferase (GGT; 40%), proteinuria (40%), increased blood bilirubin (BB; 36%), abnormal electrocardiogram T wave (36%), hypertension (36%), palmar-plantar erythrodysesthesia syndrome (32%), increased CK-myocardial band isozyme (CK-MB; 28%), hyperuricemia (28%), upper abdominal pain (24%), vomiting (24%), and hypokalemia (20%);

- Twelve patients (48%) experienced at least one Grade ≥3 TEAE, with the most common (≥5%) being hypertension (12%), increased ALT (8%), and increased GGT (8%);

- One patient (4%) experienced a serious TEAE of anal abscess, associated with sitravatinib;

- Treatment discontinuation due to TEAEs occurred in two patients (8%), with one discontinuing tislelizumab due to vaginal hemorrhage (unrelated to tislelizumab) and the other sitravatinib due to increased BCK (related to sitravatinib);

- Dose interruptions and reductions of sitravatinib occurred in 18 patients (72%) and 13 patients (52%), respectively;
- All 25 patients were evaluable for efficacy and the confirmed ORR was 24% (95% CI: 9.4, 45.1), including six partial responses (PRs), and the disease control rate (DCR) was 88% (95% CI: 68.8, 97.5); and
- The media duration of response (DoR) was not reached, and the investigator-assessed median PFS was 6.7 months (95% CI: 4.07, not evaluable).

Results in Patients with Advanced PROC

“It’s common to see patients with ovarian cancer become refractory or resistant to platinum-based therapy after receiving the current standard of care. The combination of sitravatinib and tislelizumab was generally well tolerated and showed promising antitumor activity among patients with advanced PROC, including those who were heavily pretreated. While the sample size is relatively small, we look forward to further evaluating this novel combination in PROC,” said Jeffrey Goh, MBBS, FRACP, Medical Oncologist at Icon Cancer Centre in Australia.

At the time of data cutoff on October 13, 2020, a total of 60 patients with recurrent PROC who had no prior exposure to anti-PD-1/L1 antibodies had been enrolled in cohort E of the Phase 1b trial and 13 of them (22%) remained on study treatment. These patients received a median of four (range: 1, 11) prior regimens. With a median follow-up time of six months, results included:

- Fifty-eight patients (97%) experienced at least one TEAE of any grade, with the most common (≥20%) being diarrhea (67%), nausea (57%), fatigue (48%), hypertension (40%), decreased appetite (37%), vomiting (37%), abdominal pain (35%), constipation (33%), increased ALT (30%), urinary tract infection (27%), increased AST (20%), dysphonia (20%), headache (20%), and palmar-plantar erythrodysesthesia syndrome (20%);
- Forty-one patients (68%) experienced at least one Grade ≥3 TEAE, with the most common (≥10%) being hypertension (18%) and abdominal pain (12%);
- Forty-two patients (70%) experienced at least one serious TEAE;
- Treatment discontinuation due to TEAEs occurred in 23 patients (38%), with nine patients (15%) discontinuing tislelizumab and 14 (23%) sitravatinib;
- Dose interruptions and reductions of sitravatinib occurred in 50 patients (83%) and 30 patients (50%), respectively, and dose interruption of tislelizumab occurred in one patient (2%);
- Four fatal TEAEs were reported, with none considered related to study treatment;
- Among the 53 patients who were evaluable for efficacy, the confirmed ORR was 26% (95% CI: 15.3, 40.3), including 14 PRs, and the DCR was 77% (95% CI: 63.8, 87.7);
- The median DoR was 4.7 months (95% CI: 2.8, not estimable); and
- The median PFS and OS was 4.1 months (95% CI: 4.0, 5.1) and 12.9 months (95% CI: 6.3, 17.2), respectively.

About Sitravatinib

Sitravatinib is an investigational, spectrum-selective receptor tyrosine kinase (RTK) inhibitor that can potentially stimulate the body's immune response to fight cancer. Sitravatinib targets the VEGFR and TAM (TYRO3, AXL, MERTK) receptor families, which are implicated in orchestrating an immunosuppressive tumor microenvironment (TME). Inhibiting these receptors has been shown to stimulate an anti-tumor immune response and potentially re-sensitize patients to checkpoint inhibitor (CPI) therapy in patients who previously developed resistance to CPI therapy. By targeting specific RTKs with sitravatinib, the immunosuppressive TME is converted to an immune-supportive TME, and combining with CPI therapy may help regain an immune response potentially overcoming resistance to CPI therapy. Sitravatinib is being evaluated in multiple clinical trials, including the Phase 3 SAPPHIRE study, in patients with advanced non-small cell lung cancer who are resistant to CPI therapy, and certain patients who are naïve to CPI therapy.

For more information visit www.mirati.com/science.

About Tislelizumab

Tislelizumab (BGB-A317) is a humanized IgG4 anti-PD-1 monoclonal antibody specifically designed to minimize binding to FcγR on macrophages. In pre-clinical studies, binding to FcγR 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.

The China National Medical Products Administration (NMPA) has granted tislelizumab full approval for first-line treatment of patients with advanced squamous non-small cell lung cancer (NSCLC) in combination with chemotherapy. Tislelizumab has also received conditional approval from the NMPA for the treatment of patients with classical Hodgkin's lymphoma (cHL) who received at least two prior therapies, and for the treatment of patients with locally advanced or metastatic urothelial carcinoma (UC) with PD-L1 high expression whose disease progressed during or following platinum-containing chemotherapy or within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy. Full approval for these indications is contingent upon results from ongoing randomized, controlled confirmatory clinical trials.

In addition, three supplemental Biologics License Applications for tislelizumab have been accepted by the Center for Drug Evaluation (CDE) of the NMPA and are under review for first-line treatment of patients with advanced non-squamous NSCLC in combination with chemotherapy, for the second- or third-line treatment of patients with locally advanced or metastatic NSCLC who progressed on prior platinum-based chemotherapy, and for previously treated unresectable hepatocellular carcinoma.

Currently, 16 potentially registration-enabling clinical trials are being conducted in China and globally, including 13 Phase 3 trials and three pivotal Phase 2 trials.

In January 2021, BeiGene and Novartis entered into a collaboration and license agreement granting Novartis rights to develop, manufacture, and commercialize tislelizumab in North America, Europe, and Japan.

Tislelizumab is not approved for use outside of China.

About the Tislelizumab Clinical Program

Clinical trials of tislelizumab include:

- Phase 3 trial comparing tislelizumab with docetaxel in the second- or third-line setting in patients with NSCLC (NCT03358875);
- Phase 3 trial comparing tislelizumab to salvage chemotherapy in patients with relapsed/refractory classical Hodgkin Lymphoma (NCT04486391);
- Phase 3 trial in patients with locally advanced or metastatic urothelial carcinoma (NCT03967977);
- Phase 3 trial of tislelizumab in combination with chemotherapy versus chemotherapy as first-line treatment for patients with advanced squamous NSCLC (NCT03594747);

- Phase 3 trial of tislelizumab in combination with chemotherapy versus chemotherapy as first-line treatment for patients with advanced non-squamous NSCLC (NCT03663205);
- Phase 3 trial of tislelizumab in combination with platinum-based doublet chemotherapy as neoadjuvant treatment for patients with NSCLC (NCT04379635);
- Phase 3 trial of tislelizumab combined with platinum and etoposide versus placebo combined with platinum and etoposide in patients with extensive-stage small cell lung cancer (NCT04005716);
- Phase 3 trial comparing tislelizumab with sorafenib as first-line treatment for patients with hepatocellular carcinoma (HCC; NCT03412773);
- Phase 2 trial in patients with previously treated unresectable HCC (NCT03419897);
- Phase 2 trial in patients with locally advanced or metastatic urothelial bladder cancer (NCT04004221);
- Phase 3 trial comparing tislelizumab with chemotherapy as second-line treatment for patients with advanced esophageal squamous cell carcinoma (ESCC; NCT03430843);
- Phase 3 trial of tislelizumab in combination with chemotherapy as first-line treatment for patients with ESCC (NCT03783442);
- Phase 3 trial of tislelizumab versus placebo in combination with chemoradiotherapy in patients with localized ESCC (NCT03957590);
- Phase 3 trial of tislelizumab combined with chemotherapy versus placebo combined with chemotherapy as first-line treatment for patients with gastric cancer (NCT03777657);
- Phase 2 trial in patients with MSI-H/dMMR solid tumors (NCT03736889); and
- Phase 3 trial of tislelizumab combined with chemotherapy versus placebo combined with chemotherapy as first-line treatment in patients with nasopharyngeal cancer (NCT03924986).

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 5,400+ employees around the world are committed to expediting the development of a diverse pipeline of novel therapeutics. We currently market two internally discovered oncology medicines: 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 additional oncology products in China licensed from Amgen Inc.; Celgene Logistics Sàrl, a Bristol Myers Squibb (BMS) company; and EUSA Pharma; and have entered a collaboration with Novartis Pharma AG granting Novartis rights to develop, manufacture, and commercialize tislelizumab in North America, Europe, and Japan. To learn more about BeiGene, please visit www.beigene.com and follow us on Twitter at @BeiGeneUSA.

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 data from the Phase 1b trial of sitravatinib in combination with tislelizumab and the potential clinical benefits that may be demonstrated in further development, the statements about sitravatinib under the caption “About Sitravatinib”, and BeiGene's advancement, anticipated clinical development, regulatory milestones and commercialization of tislelizumab, including the combination of sitravatinib and tislelizumab. 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; 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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Exhibit 99.2

BeiGene Presents Interim Analysis Results of RATIONALE 303 Trial of Tislelizumab in Second- or Third-Line Non-Small Cell Lung Cancer at the AACR Annual Meeting 2021

The global Phase 3 trial achieved its primary endpoint, with tislelizumab significantly prolonging overall survival in all patients, regardless of PD-L1 status;

Tislelizumab was generally well-tolerated, consistent with known risks;

A supplemental biologics license application for tislelizumab in this indication was accepted for review in China in March 2021

CAMBRIDGE, Mass. and BEIJING, China, April 12, 2021 -- BeiGene, Ltd. (NASDAQ: BGNE; HKEX: 06160), a commercial-stage biotechnology company focused on developing and commercializing innovative medicines worldwide, today announced results from a planned interim analysis of the Phase 3 RATIONALE 303 trial of its anti-PD-1 antibody tislelizumab compared to docetaxel as second- or third-line therapy for patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) in an oral presentation at the American Association for Cancer Research (AACR) Annual Meeting 2021. A supplemental biologics application (sBLA) based on these results from the RATIONALE 303 trial was accepted in March 2021 and is currently under regulatory review in China.

“Tislelizumab continues to demonstrate its potential in delivering meaningful survival benefit to patients with advanced or metastatic NSCLC in both the second- and third-line setting, as shown in today’s reported results, as well as with treatment-naïve populations as previously reported at last year’s ASCO and ESMO meetings,” commented Yong (Ben) Ben, M.D., Chief Medical Officer, Immuno-Oncology at BeiGene. “In addition, tislelizumab was generally well-tolerated, consistent with known risks from previously reported results across different tumor types. These encouraging results from RATIONALE 303, which supported the recently accepted sBLA in second- or third-line NSCLC in China, further suggest that tislelizumab is a potentially differentiated checkpoint inhibitor.”

Interim Analysis Results from Phase 3 RATIONALE 303 Trial of Tislelizumab vs. Docetaxel in Second- or Third-Line Locally Advanced or Metastatic NSCLC

Presentation Number: CT039

RATIONALE 303 is a randomized, open-label, multicenter global Phase 3 trial (NCT03358875) designed to evaluate the efficacy and safety of tislelizumab compared to docetaxel in the second- or third-line setting in patients with locally advanced or metastatic NSCLC who have progressed on prior platinum-based chemotherapy. The dual primary endpoints of the trial are overall survival (OS) in intent-to-treat (ITT) patients and OS in patients with high PD-L1 expression; key secondary endpoints include objective response rate (ORR), duration of response (DoR), progression-free survival (PFS), and safety. A total of 805 patients in 10 countries across Asia, Europe, the Americas, and Oceania were enrolled in the trial. Patients were randomized 2:1 to either the tislelizumab arm or the docetaxel arm.

“Based on the RATIONALE 303 trial results, compared to docetaxel standard of care, tislelizumab significantly prolonged the median OS by more than five months in all patients and was able to yield a consistent OS benefit across all patients, regardless of PD-L1 status,” said Caicun Zhou, M.D., Ph.D., Director of the Department of Oncology at Shanghai Pulmonary Hospital and Director of Cancer Institute of Tongji University. “Tislelizumab was also tolerated among these patients, with a notably lower incidence rate of Grade ≥3 adverse events compared to docetaxel. We’re encouraged by the promising findings presented today and hope tislelizumab could become an important treatment option for second- or third-line NSCLC patients.”

A pre-specified OS interim analysis in the ITT patient population was performed at the data cutoff as of August 10, 2020, and evaluated by the independent data monitoring committee.

In the interim analysis, RATIONALE 303 achieved the primary endpoint of OS in the ITT population. Key efficacy results included:

- In the ITT population, the median OS was 17.2 months (95% CI: 15.28, 20.04) in the tislelizumab arm, a significant improvement compared to 11.9 months (95% CI: 10.18, 13.93) in the docetaxel arm (p <0.0001; hazard ratio [HR]=0.64 [95%CI: 0.527, 0.778]);
- In the PD-L1 high population, the median OS was 19.1 months (95% CI: 16.82, 25.79), a significant improvement compared to 11.9 months (95% CI: 8.90, 14.03) in the docetaxel arm (*descriptive* p <0.0001; HR = 0.52 [95% CI: 0.384, 0.713]);

- The median PFS in the tislelizumab arm was 4.1 months (95% CI: 3.75, 5.03), compared to 2.6 months (95% CI: 2.17, 3.78) in the docetaxel arm (*descriptive p* <0.0001; HR = 0.64 [95% CI: 0.533, 0.758]);
- The PFS rate at 12 months was 23.3% in the tislelizumab arm, compared to 5.7% in the docetaxel arm;
- The ORR in the tislelizumab arm was 21.9%, compared to 7.0% in the docetaxel arm, with a difference of 14.9% (95% CI: 10.26, 19.56; *descriptive p* <0.0001); and
- The median DoR in the tislelizumab arm and the docetaxel arm was 13.5 months (95% CI: 8.54, 21.78) and 6.2 months (95% CI: 2.10, 7.16), respectively.

In the interim analysis, tislelizumab showed a safety profile consistent with data previously observed in other tislelizumab monotherapy studies as well as other PD-1/L1 inhibitors. Overall safety results included:

- In the tislelizumab arm, 509 patients (95.3%) experienced at least one treatment-emergent adverse event (TEAE) with the most common being anemia (28.5%), increased alanine aminotransferase (ALT; 19.9%), and cough (19.5%), compared to 254 patients (98.4%) in the docetaxel arm with the most common being alopecia (47.3%), anemia (43.4%), and decreased neutrophil count (36.8%);
- Grade ≥3 TEAEs were reported in 206 patients (38.6%) and 193 patients (74.8%) in the tislelizumab arm and docetaxel arm, respectively;
- Serious TEAEs were reported in 174 patients (32.6%) and 83 patients (32.2%) in the tislelizumab arm and docetaxel arm, respectively;
- Fifty-six patients (10.5%) and 32 patients (12.4%) discontinued treatment due to TEAEs in the tislelizumab arm and docetaxel arm, respectively;
- Thirty-two patients (6.0%) and 11 patients (4.3%) experienced a fatal TEAE in the tislelizumab arm and docetaxel arm, respectively; and
- In the tislelizumab arm, hypothyroidism (7.5%) and pneumonitis (2.2%) were the most common immune-mediated TEAEs of any grade and of Grade ≥3, respectively.

About Non-Small Cell Lung Cancer

Lung cancer remains the second most common type of cancer and the leading cause of cancer-related death worldwide.[i] NSCLC accounts for approximately 85% of all lung cancer cases and is usually diagnosed at an advanced stage.[ii] The five-year survival rate with treatment for stage IIIB and stage IV NSCLC is 5% and 2%, respectively.[iii] In China, the lung cancer incidence rate is increasing, with approximately 815,563 new cases in 2020.[iv,v]

About Tislelizumab

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The China National Medical Products Administration (NMPA) has granted tislelizumab full approval for first-line treatment of patients with advanced squamous non-small cell lung cancer (NSCLC) in combination with chemotherapy. Tislelizumab has also received conditional approval from the NMPA for the treatment of patients with classical Hodgkin's lymphoma (cHL) who received at least two prior therapies, and for the treatment of patients with locally advanced or metastatic urothelial carcinoma (UC) with PD-L1 high expression whose disease progressed during or following platinum-containing chemotherapy or within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy. Full approval for these indications is contingent upon results from ongoing randomized, controlled confirmatory clinical trials.

In addition, three supplemental Biologics License Applications for tislelizumab have been accepted by the Center for Drug Evaluation (CDE) of the NMPA and are under review for first-line treatment of patients with advanced non-squamous NSCLC in combination with chemotherapy, for the second- or third-line treatment of patients with locally advanced or metastatic NSCLC who progressed on prior platinum-based chemotherapy, and for previously treated unresectable hepatocellular carcinoma.

Currently, 16 filed or potentially registration-enabling clinical trials are being conducted in China and globally, including 13 Phase 3 trials and three pivotal Phase 2 trials.

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- Phase 3 trial of tislelizumab in combination with chemotherapy versus chemotherapy as first-line treatment for patients with advanced squamous NSCLC (NCT03594747);
- Phase 3 trial of tislelizumab in combination with chemotherapy versus chemotherapy as first-line treatment for patients with advanced non-squamous NSCLC (NCT03663205);
- Phase 3 trial of tislelizumab in combination with platinum-based doublet chemotherapy as neoadjuvant treatment for patients with NSCLC (NCT04379635);
- Phase 3 trial of tislelizumab combined with platinum and etoposide versus placebo combined with platinum and etoposide in patients with extensive-stage small cell lung cancer (NCT04005716);
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- Phase 2 trial in patients with previously treated unresectable HCC (NCT03419897);
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- Phase 3 trial comparing tislelizumab with chemotherapy as second-line treatment for patients with advanced esophageal squamous cell carcinoma (ESCC; NCT03430843);
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- Phase 3 trial of tislelizumab versus placebo in combination with chemoradiotherapy in patients with localized ESCC (NCT03957590);
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- Phase 3 trial of tislelizumab combined with chemotherapy versus placebo combined with chemotherapy as first-line treatment in patients with nasopharyngeal cancer (NCT03924986).

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 5,400+ employees around the world are committed to expediting the development of a diverse pipeline of novel therapeutics. We currently market two internally discovered oncology medicines: 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 additional oncology products in China licensed from Amgen Inc.; Celgene Logistics Sàrl, a Bristol Myers Squibb (BMS) company; and EUSA Pharma; and have entered a collaboration with Novartis Pharma AG granting Novartis rights to develop, manufacture, and commercialize tislelizumab in North America, Europe, and Japan. To learn more about BeiGene, please visit www.beigene.com and follow us on Twitter at @BeiGeneUSA.

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 data from the RATIONALE-303 trial of tislelizumab compared to docetaxel in the second- or third-line setting in patients with locally advanced or metastatic non-small cell lung cancer who have progressed on prior platinum-based chemotherapy, the filing and potential approval of an sBLA in China based on this data, and BeiGene's advancement, anticipated clinical development, regulatory milestones and commercialization of tislelizumab. 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; 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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