BeiGene, Ltd.
百濟神州有限公司
(incorporated in the Cayman Islands with limited liability)
(Stock Code: 06160)

VOLUNTARY ANNOUNCEMENT – UPDATE REGARDING RECENT BUSINESS DEVELOPMENTS

BEIGENE PRESENTS UPDATED HEAD TO HEAD RESULTS FROM PHASE 3 TRIAL OF ZANUBRUTINIB VS. IBRUTINIB IN PATIENTS WITH WALDENSTRÖM'S MACROGLOBULINEMIA AT THE 2020 AMERICAN SOCIETY OF CLINICAL ONCOLOGY (ASCO) VIRTUAL SCIENTIFIC PROGRAM

On May 29, 2020, BeiGene, Ltd. ("**BeiGene**" or the "**Company**"), a commercial-stage biotechnology company focused on developing and commercializing innovative molecularly-targeted and immuno-oncology drugs for the treatment of cancer, announced follow-up data from the Phase 3 ASPEN trial comparing BRUKINSA™ (zanubrutinib) to ibrutinib for the treatment of Waldenström's macroglobulinemia (WM) and long-term follow-up data from a Phase 1/2 study in patients with treatment naïve and relapsed/refractory (R/R) WM, presented at the 2020 American Society of Clinical Oncology (ASCO) Virtual Scientific Program.

"The totality of data from the two trials presented at ASCO suggests that zanubrutinib may be a preferred treatment option for patients with WM, regardless of whether they have received prior treatment," said Constantine S. Tam, MBBS, M.D., Disease Group Lead for Low Grade Lymphoma and Chronic Lymphocytic Leukemia at the Peter MacCallum Cancer Center, Australia, and a member of the steering committee and principal investigator for the ASPEN trial. "WM can be a devastating disease for patients and their families. We must offer therapies that are both effective in managing WM and well-tolerated to offer the best quality of life. In the ASPEN trial, zanubrutinib demonstrated a more favorable safety profile and was shown to be a more tolerable option for patients than ibrutinib, especially when considering adverse events of particular interest such as atrial fibrillation, hypertension and diarrhea."

While the ASPEN trial did not achieve statistical significance on its primary endpoint of superiority in complete response (CR) and very good partial response (VGPR) rates for zanubrutinib compared to ibrutinib, zanubrutinib demonstrated a numerically higher VGPR rate, as well as clinically meaningful improvements in safety and tolerability compared to ibrutinib. Additional five-month investigator-assessed follow-up data in the overall patient population reinforced the trend toward higher VGPR rates for zanubrutinib and advantages in safety. In a separate presentation of Phase 1/2 long-term follow-up data, rates of VGPR/CR increased with continued zanubrutinib treatment and the therapy was well tolerated.

"These results reinforce that zanubrutinib is a highly effective BTK inhibitor with clinically meaningful improvements in safety and tolerability compared to ibrutinib. Importantly, since WM is typically a disease of older individuals, zanubrutinib appears to have advantages related to cardiovascular safety risks over ibrutinib," said Jane Huang, M.D., Chief Medical Officer, Hematology at BeiGene. "The choice to evaluate zanubrutinib directly against ibrutinib underscores our bold approach to R&D and our commitment to develop better treatments for patients across the globe."

ASPEN Trial Data
Oral Presentation, Abstract #8007

Data presented from the Phase 3 ASPEN trial (NCT03053440) include the 201 patients in the randomized cohort of patients with WM and a MYD88 mutation.

- At data cutoff of August 31, 2019, with 19.4 months median follow-up:
    - The combined CR+VGPR rate as assessed by independent review committee (IRC) for the overall intent-to-treat population was 28.4% in the zanubrutinib arm and 19.2% in the ibrutinib arm (2-sided descriptive p=0.0921);
    - The combined CR+VGPR rate as assessed by investigators for the overall intent-to-treat population was 28.4% in the zanubrutinib arm and 17.2% in the ibrutinib arm (2-sided descriptive p=0.0437);
    - Most common grade ≥ 3 adverse events (≥5% in either arm) for zanubrutinib compared to ibrutinib included hypertension (6% vs. 11%), neutropenia (16% vs. 8%), pneumonia (1% vs. 7%), anemia (5% vs. 5%), and thrombocytopenia (5% vs. 3%);
    - Categories of AEs of interest for BTK inhibitors for zanubrutinib compared to ibrutinib included atrial fibrillation/flutter of any grade (2.0% vs. 15.3%), bleeding of any grade (48.5% vs. 59.2%), major hemorrhage (5.9% vs. 9.2%), diarrhea (20.8% vs. 31.6%), hypertension (10.9% vs. 17.3%); neutropenia (29.7% vs. 13.3%), infection (66.3% vs. 67.3%), and second malignancy (11.9% vs. 11.2%);
    - Despite higher rates of grade ≥ 3 neutropenia among AEs of interest in the zanubrutinib arm (19.8% vs. 8.2% for ibrutinib), rates of infection were similar in patients taking zanubrutinib and ibrutinib (all grades: 66.3% vs. 67.3%; grade ≥ 3: 17.8% vs. 19.4%); and
    - In the zanubrutinib arm, four (4.0%) patients discontinued treatment due to AEs and one (1.0%) patient had an adverse event leading to death; in the ibrutinib arm, nine patients (9.2%) discontinued due to AEs and four (4.1%) patients had an adverse event leading to death.

- After an additional five-months of follow-up with a data cutoff of January 31, 2020, with 24.2 months median follow-up:

    - o CR+VGPR as assessed by investigator for zanubrutinib was 30.4% compared to 18.2% for ibrutinib (exploratory analysis; 2-sided descriptive p=0.0302);

    - o Categories of AEs of interest for BTK inhibitors for zanubrutinib compared to ibrutinib included atrial fibrillation/flutter of any grade (3.0% vs. 18.4%), bleeding of any grade (50.5% vs. 60.2%), major hemorrhage (5.9% vs. 10.2%), diarrhea (21.8% vs. 32.7%), hypertension (12.9% vs. 20.4%); and neutropenia (31.7% vs. 15.3%);

    - o Despite higher rates of grade ≥ 3 neutropenia in the zanubrutinib arm (22.8% vs. 8.2% for ibrutinib), rates of infection remained similar in patients taking zanubrutinib and ibrutinib (all grade: 69.3% vs. 71.4%; grade ≥ 3: 18.8% vs. 23.5%); and

    - o No additional patients discontinued treatment due to AEs in the zanubrutinib arm, compared to an additional five patients in the ibrutinib arm (4% vs 14.3%). No additional patients had an adverse event leading to death in both arms (1.0% vs. 4.1%).

ASPEN Data from Non-Randomized Cohort, Patients with MYD88 Wild-Type (MYD88wt) WM

Electronic Abstract #20056

Additional data from the ASPEN trial presented in an abstract included 28 patients who were centrally determined at study entry to have the *MYD88WT* or mutation unknown genotype. These patients were enrolled into a non-randomized cohort assigned to receive zanubrutinib 160mg twice daily (BID).

As of August 31, 2019, the median follow-up was 17.9 months and 17 patients remained on study treatment. Updated results included:

- In the 26 centrally confirmed MYD88WT patients, the overall response rate (ORR) assessed by IRC was 80.8%, with a major response rate of 50.0%, including a VGPR rate of 26.9%;

- Progression-free survival (PFS) event-free rate at 12 months was 72.4%;

- In this cohort of 28 patients with MYD88WT or mutation unknown genotype, the most frequently reported AEs (≥ 20%) were diarrhea, anemia, contusion, pyrexia, and upper respiratory tract infection. Major hemorrhage was reported in 2 patients, and atrial fibrillation was reported in 1 patient. There were no fatal AEs; and

- Two patients (7.1%) discontinued zanubrutinib due to adverse events, and 6 patients (14.3%) discontinued due to disease progression.

Phase 1/2 Trial Data
Poster Presentation, Abstract #8051

Data presented from the Phase 1/2 trial (NCT02343120) evaluating zanubrutinib in patients with treatment-naïve or relapsed/refractory WM include:

- As of January 29, 2020, with a median follow-up of 35.3 months, 73% remained on treatment;
- The ORR was 96% and the VGPR/CR rate was 46%;
- The proportion of patients achieving a best response of VGPR or CR increased with treatment duration;
- Three-year PFS event-free rate was 80%, and overall survival was 83%;
- Reasons for treatment discontinuation included AEs in 13% of patients, disease progression in 10%, and other in 4%;
- The most commonly reported AEs (≥ 20%) were upper respiratory tract infection (55%), contusion (33%, all grade 1), cough (23%), and diarrhea (21%);
- 62.3% of patients (48/77) experienced at least one grade ≥3 AE and five patients experienced AEs leading to death;
- AEs of interest included minor bleeding (35%), hypertension (18%), major hemorrhage (5%), and atrial fibrillation/flutter (5%).

Investor Conference Call

The Company hosted an investor conference call and webcast on Friday, May 29, 2020 at 8:00 p.m. ET to discuss results presented at the ASCO Virtual Scientific Program.

A live webcast of the conference call can be accessed from the investors section of BeiGene's website at http://ir.beigene.com or http://hkexir.beigene.com. An archived replay will be available for 90 days following the event.

To learn more about BeiGene's pipeline and data presented during the ASCO2020 Virtual Scientific Program, visit BeiGeneVirtualCongress.com.

About Waldenström's Macroglobulinemia

WM is a rare lymphoma representing approximately 1% of all non-Hodgkin lymphomas and typically progresses slowly after diagnosis.[i] In the United States, approximately 3,000 people are diagnosed with WM each year.[i]

About the ASPEN Trial

The Phase 3 randomized, open-label, multicenter ASPEN clinical trial (NCT03053440) evaluated zanubrutinib versus ibrutinib in patients with relapsed/refractory (R/R) or treatment-naïve (TN) Waldenström's macroglobulinemia. The primary objective was to establish superiority of zanubrutinib compared to ibrutinib as demonstrated by the proportion of patients achieving complete response (CR) or very good partial response (VGPR). Secondary endpoints included major response rate, duration of response and progression-free survival, and safety, measured by incidence, timing and severity of treatment-emergent adverse events. The pre-specified analysis populations for the trial included the overall population (n=201) and R/R patients (n=164). Exploratory endpoints included quality of life measures.

The study included two cohorts, a randomized cohort (cohort 1) consisting of 201 patients with a MYD88 mutation and a non-randomized cohort (cohort 2) in which 28 patients with MYD88 wild-type (MYD88WT) received zanubrutinib because they have historically responded poorly to ibrutinib therapy.

The randomized cohort 1 enrolled 102 patients (including 83 relapsed or refractory (R/R) patients and 19 treatment-naïve (TN) patients) in the zanubrutinib arm and 99 patients (including 81 R/R patients and 18 TN patients) in the ibrutinib arm. Patients in the zanubrutinib arm were assigned to receive zanubrutinib 160 mg twice daily (BID) and patients in the ibrutinib arm received 420 mg of ibrutinib once daily (QD).

About the Zanubrutinib Clinical Trial Program

Clinical trials of zanubrutinib include:

- Fully-enrolled Phase 3 ASPEN clinical trial in patients with Waldenström's macroglobulinemia (WM) comparing zanubrutinib to ibrutinib (NCT03053440), currently the only approved BTK inhibitor for WM;
- Phase 3 SEQUOIA trial comparing zanubrutinib with bendamustine plus rituximab in patients with treatment-naive (TN) chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) (NCT03336333);
- Phase 3 ALPINE trial comparing zanubrutinib to ibrutinib in patients with relapsed/refractory (R/R) CLL/SLL (NCT03734016);
- Phase 2 trial in combination with GAZYVA® (obinutuzumab) in patients with R/R follicular lymphoma (FL) (NCT03332017);
- Phase 3 trial comparing zanubrutinib and rituximab to bendamustine and rituximab in patients with untreated MCL (NCT04002297);
- Phase 2 MAGNOLIA trial in patients with R/R marginal zone lymphoma (MZL) (NCT03846427);
- Phase 2 ROSEWOOD trial (NCT03332017) in China comparing obinutuzumab and zanubrutinib vs obinutuzumab alone in treating patients with R/R FL;

- Phase 2 trial (NCT04382586) in the U.S. comparing zanubrutinib plus supportive care to placebo plus supportive care for the treatment of patients with COVID-19 disease and pulmonary distress;

- Phase 2 trial (NCT03332173) in China in patients with R/R WM; and

- Completed Phase 2 trials in China in patients with R/R MCL (NCT03206970) and R/R CLL/SLL (NCT03206918).

About BRUKINSA™ (zanubrutinib)

BRUKINSA is a small molecule inhibitor of Bruton's tyrosine kinase (BTK), discovered by BeiGene scientists, that is currently being evaluated globally in a broad pivotal clinical program as a monotherapy and in combination with other therapies to treat various B-cell malignancies.

BRUKINSA was approved by the U.S. FDA to treat adult patients with mantle cell lymphoma (MCL) who have received at least one prior therapy on November 14, 2019. This indication was approved under accelerated approval based on overall response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.

New Drug Applications (NDAs) in China for relapsed refractory (R/R) MCL and R/R chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) have been accepted by the China National Medical Products Administration (NMPA) and granted priority review and are pending approval.

BRUKINSA is not approved for use outside the United States. BRUKINSA is not approved for the treatment of Waldenström's macroglobulinemia.

IMPORTANT SAFETY INFORMATION FOR BRUKINSA (ZANUBRUTINIB)

Warnings and Precautions

Hemorrhage

Fatal and serious hemorrhagic events have occurred in patients with hematological malignancies treated with BRUKINSA monotherapy. Grade 3 or higher bleeding events including intracranial and gastrointestinal hemorrhage, hematuria and hemothorax have been reported in 2% of patients treated with BRUKINSA monotherapy. Bleeding events of any grade, including purpura and petechiae, occurred in 50% of patients treated with BRUKINSA monotherapy.

Bleeding events have occurred in patients with and without concomitant antiplatelet or anticoagulation therapy. Co-administration of BRUKINSA with antiplatelet or anticoagulant medications may further increase the risk of hemorrhage.

Monitor for signs and symptoms of bleeding. Discontinue BRUKINSA if intracranial hemorrhage of any grade occurs. Consider the benefit-risk of withholding BRUKINSA for 3-7 days pre- and post-surgery depending upon the type of surgery and the risk of bleeding.

Infections

Fatal and serious infections (including bacterial, viral, or fungal) and opportunistic infections have occurred in patients with hematological malignancies treated with BRUKINSA monotherapy. Grade 3 or higher infections occurred in 23% of patients treated with BRUKINSA monotherapy. The most common Grade 3 or higher infection was pneumonia. Infections due to hepatitis B virus (HBV) reactivation have occurred.

Consider prophylaxis for herpes simplex virus, pneumocystis jiroveci pneumonia and other infections according to standard of care in patients who are at increased risk for infections. Monitor and evaluate patients for fever or other signs and symptoms of infection and treat appropriately.

Cytopenias

Grade 3 or 4 cytopenias, including neutropenia (27%), thrombocytopenia (10%), and anemia (8%) based on laboratory measurements, were reported in patients treated with BRUKINSA monotherapy.

Monitor complete blood counts during treatment and treat using growth factor or transfusions, as needed.

Second Primary Malignancies

Second primary malignancies, including non-skin carcinoma, have occurred in 9% of patients treated with BRUKINSA monotherapy. The most frequent second primary malignancy was skin cancer (basal cell carcinoma and squamous cell carcinoma of skin), reported in 6% of patients. Advise patients to use sun protection.

Cardiac Arrhythmias

Atrial fibrillation and atrial flutter have occurred in 2% of patients treated with BRUKINSA monotherapy. Patients with cardiac risk factors, hypertension, and acute infections may be at increased risk. Grade 3 or higher events were reported in 0.6% of patients treated with BRUKINSA monotherapy. Monitor signs and symptoms for atrial fibrillation and atrial flutter and manage as appropriate.

Embryo-Fetal Toxicity

Based on findings in animals, BRUKINSA can cause fetal harm when administered to a pregnant woman. Administration of zanubrutinib to pregnant rats during the period of organogenesis caused embryo-fetal toxicity, including malformations at exposures that were 5 times higher than those reported in patients at the recommended dose of 160 mg twice daily. Advise women to avoid becoming pregnant while taking BRUKINSA and for at least 1 week after the last dose. Advise men to avoid fathering a child during treatment and for at least 1 week after the last dose. If this drug is used during pregnancy, or if the patient becomes pregnant while taking this drug, the patient should be apprised of the potential hazard to a fetus.

Adverse Reactions

The most common adverse reactions in > 10% of patients who received BRUKINSA were neutrophil count decreased (53%), platelet count decreased (39%), upper respiratory tract infection (38%), white blood cell count decreased (30%), hemoglobin decreased (29%), rash (25%), bruising (23%), diarrhea (20%), cough (20%), musculoskeletal pain (19%), pneumonia (18%), urinary tract infection (13%), hematuria (12%), fatigue (11%), constipation (11%), and hemorrhage (10%). The most frequent serious adverse reactions were pneumonia (11%) and hemorrhage (5%).

Of the 118 patients with MCL treated with BRUKINSA, 8 (7%) patients discontinued treatment due to adverse reactions in the trials. The most frequent adverse reaction leading to treatment discontinuation was pneumonia (3.4%). One (0.8%) patient experienced an adverse reaction leading to dose reduction (hepatitis B).

Drug Interactions

CYP3A Inhibitors: When BRUKINSA is co-administered with a strong CYP3A inhibitor, reduce BRUKINSA dose to 80 mg once daily. For co-administration with a moderate CYP3A inhibitor, reduce BRUKINSA dose to 80 mg twice daily.

CYP3A Inducers: Avoid co-administration with moderate or strong CYP3A inducers.

Specific Populations

Hepatic Impairment: The recommended dose of BRUKINSA for patients with severe hepatic impairment is 80 mg orally twice daily.

INDICATION

BRUKINSA is a kinase inhibitor indicated for the treatment of adult patients with mantle cell lymphoma (MCL) who have received at least one prior therapy.

This indication is approved under accelerated approval based on overall response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.

Please see full Prescribing Information at www.beigene.com/PDF/BRUKINSAUSPI.pdf and Patient Information at www.beigene.com/PDF/BRUKINSAUSPPI.pdf.

[i] Lymphoma Research Foundation. Getting the Facts: Waldenström Macroglobulinemia.

Accessed May 2020. Available at <https://lymphoma.org/wp-content/uploads/2018/04/LRF_FACTSHEET_WALDENSTR%C3%96M_MACROGLOBULINEMIA.pdf>.

BEIGENE PRESENTS PHASE 3 DATA ON TISLELIZUMAB COMBINED WITH CHEMOTHERAPY FOR THE TREATMENT OF PATIENTS WITH ADVANCED SQUAMOUS NON-SMALL CELL LUNG CANCER AT THE 2020 AMERICAN SOCIETY OF CLINICAL ONCOLOGY (ASCO) VIRTUAL SCIENTIFIC PROGRAM

On May 29, 2020, the Company announced results from a Phase 3 clinical trial evaluating its anti-PD-1 antibody tislelizumab in combination with standard chemotherapy for the first-line treatment of patients with advanced squamous non-small cell lung cancer (NSCLC), presented at the 2020 American Society of Clinical Oncology (ASCO) Virtual Scientific Program.

"The results from this Phase 3 trial demonstrated that inhibiting the PD-1 pathway with tislelizumab, combined with standard chemotherapy, provided a clinically meaningful benefit to patients with advanced squamous NSCLC, as assessed by progression-free survival and response rates," said Jie Wang, M.D., Ph.D., National Cancer Center/Cancer Hospital, Chinese Academy of Medical Sciences & Peking Union Medical College. "Lung cancer is the leading cause of cancer-related death in China, and with NSCLC comprising the most common form of the disease, it is critical to identify new treatments that address patient needs."

"We are excited to share data from this trial, which were included in our supplemental new drug application currently under review by the China National Medical Products Administration. Tislelizumab has been approved in China in both hematologic and solid tumor indications, and we are conducting 15 potentially registration-enabling clinical trials in China and around the world," said Yong (Ben) Ben, M.D., Chief Medical Officer, Immuno-Oncology at BeiGene. "Together with the positive results we recently announced for a second Phase 3 trial in first-line NSCLC in patients with non-squamous histology, we believe these important findings position tislelizumab to serve the large population of patients in China with advanced NSCLC, for whom we hope to bring a new treatment option as quickly as possible."

Tislelizumab was evaluated as a first-line treatment in advanced squamous NSCLC in combination with either paclitaxel and carboplatin or nab-paclitaxel (ABRAXANE®[i]) and carboplatin compared with paclitaxel and carboplatin alone in an open-label, multi-center Phase 3 trial (NCT03594747) in China. In this trial, 360 patients with histologically confirmed stage IIIB or IV NSCLC were randomized 1:1:1 to receive tislelizumab (200 mg every three weeks) in combination with each of the chemotherapy regimens or chemotherapy alone, until disease progression, unacceptable toxicity, physician decision or consent withdrawal.

As of data cutoff on December 6, 2019, data were available for 120 patients in Arm A (tislelizumab with paclitaxel and carboplatin), 119 patients in Arm B (tislelizumab with ABRAXANE® and carboplatin) and 121 patients in Arm C (paclitaxel and carboplatin alone). As of the data cutoff, 63 patients (52.5%) in Arm A and 66 patients (55.5%) in Arm B remained on treatment; 81 patients (66.9%) completed chemotherapy in Arm C.

Results included:

- The trial achieved the primary endpoint of progression-free survival (PFS) as assessed by Independent Review Committee (IRC); PFS was significantly improved with tislelizumab plus chemotherapy (Arms A and B) compared with chemotherapy alone (Arm C), regardless of tumor cell PD-L1 expression. Across all arms, median overall survival was not reached, and median number of treatment cycles were comparable;

- Median PFS was 7.6 months for both tislelizumab arms compared to 5.5 months for chemotherapy alone. The hazard ratio (HR) for the comparison of Arm A vs. Arm C was 0.52 (95% confidence interval (CI), 0.4-0.7; p=0.0001), the HR for the comparison of Arm B vs. Arm C was 0.48 (95% CI, 0.3-0.7; p <0.0001);

- Additionally, the objective response rates (ORR) were meaningfully higher for patients receiving tislelizumab; ORRs were 73% (95% CI 64%-80%) and 75% (66%-82%) in Arm A and Arm B, respectively versus 50% (40%-59%) in Arm C;

- Treatment with tislelizumab plus chemotherapy also roughly doubled the median duration of response (DoR) compared to chemotherapy alone. In the tislelizumab cohorts, DoR was 8.2 months for Arm A and 8.6 months for Arm B, while DoR in the Arm C was 4.2 months;

- Treatment with tislelizumab and chemotherapy was generally well-tolerated in patients with NSCLC and in line with the known safety profiles of tislelizumab, chemotherapy, and underlying NSCLC. No new safety signals were identified with the addition of tislelizumab to chemotherapy;

- Most treatment-related AEs (TRAEs) were mild or moderate in severity; the most common TRAEs (≥ 20%) of any grade in all patients were (Arm A, Arm B, Arm C, respectively) hematologic in nature and included anemia (82.5%; 88.1%; 74.4%), alopecia (64.2%; 68.6%; 61.5%), decreased neutrophil count (62.5%; 61.0%; 58.1%), decreased white blood cell count (52.5%; 57.6%; 53.0%), leukopenia (47.5%; 55.9%; 47.9%), neutropenia (42.5%; 42.4%; 47.0%), and decreased appetite (41.7%; 41.5%; 29.9%);

- Serious treatment-related AEs (TRAEs) were reported in 27 patients in Arm A, 28 patients in Arm B and 17 patients in Arm C; serious TRAEs reported in Arm A and Arm B, respectively, included decreased neutrophil count (n=4; n=4), febrile neutropenia (n=2; n=3), pneumonitis (n=3; n=2), leukopenia (n=2; n=1), increased blood creatine phosphokinase (n=2 Arm B), decreased platelet count (n=1; n=2), bone marrow failure (n=2; n=1), rash (n=2 Arm A), and pyrexia (n=2 Arm A). The most commonly reported TRAEs in Arm C were thrombocytopenia (n=3) and decreased neutrophil count, decreased white blood cell count, and septic shock (n=2 each);

- Tislelizumab-related grade ≥3 AEs occurred in 36.7% and 40.7% of patients in Arm A and Arm B, respectively;

- Treatment-emergent AEs (TEAEs) leading to death were reported in 4 patients (3.3%) in Arm A, 5 patients (4.2%) in Arm B, and 5 patients (4.3%) in Arm C; and

- Potential immune-mediated AEs occurred in 51.7% (A), 47.5% (B), and 18.8% (C) of patients. Most were low grade, did not require corticosteroid treatments, and did not lead to discontinuation of any treatment component. The most commonly reported immune-mediated AE was pneumonitis; grade ≥3 pneumonitis occurred in 2.5%, 3.4%, and 0.9% of patients in Arms A, B, and C, respectively.

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The Company hosted an investor conference call and webcast on Friday, May 29, 2020 at 8:00 p.m. ET to discuss results presented at the ASCO Virtual Scientific Program.

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About Non-Small Cell Lung Cancer

In contrast to most Western countries where lung cancer death rates are decreasing, the lung cancer incidence rate is still increasing in China.[ii, iii] In 2018, there were approximately 770,000 new cases of lung cancer in China and it is the leading cause of cancer-related death in both men and women, with approximately 690,500 deaths.[iv] Non-small cell lung cancer (NSCLC) comprises the most common form of lung cancer in China. [v]

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.

Tislelizumab is approved by the China National Medical Products Administration as a treatment for patients with classical Hodgkin's lymphoma who received at least two prior therapies and for 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. Additionally, the Center for Drug Evaluation (CDE) of the China National Medical Products Administration (NMPA) has accepted a supplemental new drug application (sNDA) of BeiGene's anti-PD-1 antibody tislelizumab in combination with two chemotherapy regimens for first-line treatment of patients with advanced squamous non-small cell lung cancer (NSCLC).

Currently, 15 potentially registration-enabling clinical trials are being conducted in China and globally, including 11 Phase 3 trials and four pivotal Phase 2 trials.

Tislelizumab is not approved for use outside of China and is not approved to treat non-small cell lung cancer.

[i] ABRAXANE® is a registered trademark of Abraxis Bioscience LLC, a Bristol-Myers Squibb company.

[ii] Jemal A, Bray F, Center MM, et al. Global cancer statistics. CA Cancer J Clin 2011; 61:69-90.

[iii] She J, Yang P, Hong Q, et al. Lung cancer in China: challenges and interventions. Chest 2013; 143:1117-26.

[iv] Feng et al. Cancer Communications (2019) 39:22 https://doi.org/10.1186/s40880-019-0368-6

[v] Siegel R, DeSantis C, Virgo K, et al. Cancer treatment and survivorship statistics, 2012. CA Cancer J Clin 2012; 62:220-41.

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 3,800+ employees in China, the United States, Australia, and Europe are committed to expediting the development of a diverse pipeline of novel therapeutics for cancer. We currently market two internally-discovered oncology products: BTK inhibitor BRUKINSA™ (zanubrutinib) in the United States, 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.

Forward-Looking Statements

This announcement contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 and other federal securities laws, including statements regarding clinical data for patients from the ASPEN trial and advantages compared to ibrutinib; plans for regulatory discussions and submission of data from the ASPEN trial; data from ongoing clinical trials of tislelizumab, the mechanism of action of tislelizumab; BeiGene's further advancement of, and anticipated clinical development, regulatory milestones and commercialization of its drug candidates; and continuing and further development and commercialization efforts and transactions with third parties. 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; the impact of the COVID-19 pandemic on the Company's clinical development, commercial 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 and The Stock Exchange of Hong Kong Limited. All information in this announcement is as of the date of this announcement, and BeiGene undertakes no duty to update such information unless required by law.

By order of the Board
BeiGene, Ltd.
Mr. John V. Oyler
Chairman

Hong Kong, June 2, 2020

As at the date of this announcement, the Board of Directors of the Company comprises Mr. John V. *Oyler as Chairman and Executive Director, Dr. Xiaodong Wang and Mr. Anthony C. Hooper as Non-executive Directors, and Mr. Timothy Chen, Mr. Donald W. Glazer, Mr. Michael Goller, Mr. Ranjeev Krishana, Mr. Thomas Malley, Mr. Jing-Shyh (Sam) Su and Mr. Qingqing Yi as Independent Non-executive Directors.*