BeiGene Presents Pioneering Cancer Research at ASCO 2025 – Redefining Treatment Across Hematology and Solid Tumors

New data from SEQUOIA, to be reported in two oral presentations, underscore the benefits of BRUKINSA® as first-line treatment for patients with chronic lymphocytic leukemia (CLL)

Promising early phase data show the strength of the pipeline in treating multiple solid tumor types including breast cancer

Data reinforces well-characterized efficacy and safety profile of TEVIMBRA® as a uniquely designed PD-1 inhibitor

SAN CARLOS, Calif. – May 22, 2025 – BeiGene, Ltd. (NASDAQ: ONC; HKEX: 06160; SSE: 688235), a global oncology company that will change its name to BeOne Medicines Ltd., today announced it will share 23 abstracts featuring new data across its hematology and solid tumor portfolio at the American Society of Clinical Oncology (ASCO) Annual Meeting in Chicago, IL, May 30 – June 3, 2025. With two abstracts selected for rapid oral presentation, these data reflect the Company's vision to address cancer across multiple fronts and provide innovative medicines to as many patients as possible worldwide.

"ASCO is a powerful platform for highlighting progress in cancer care, and we're proud to contribute 23 accepted abstracts that reflect our mission to improve outcomes for more patients around the world," said Mark Lanasa, M.D., Ph.D., Chief Medical Officer, Solid Tumors at BeiGene. "From long-term follow-up results for BRUKINSA in CLL to first-time clinical data for two promising breast cancer assets, our presentations this year speak to the depth and momentum of our oncology portfolio — and our commitment to delivering transformative medicines across a range of cancers."

Presentations feature the impressive clinical profile of BRUKINSA (zanubrutinib) across broad patient populations; notable highlights include:

- Long-term data from SEQUOIA Arm C, which evaluated BRUKINSA in patients with treatment naïve (TN) chronic lymphocytic leukemia/small lymphocytic lymphoma (CLL/SLL) with del(17p) mutations.
- First results from the full population from Arm D of the SEQUOIA study, which evaluated BRUKINSA plus venetoclax in patients with TN CLL/SLL with and without del (17p) and/or *TP53* mutation.
- Robust analyses across clinical trials and real-world evidence that deepen understanding of treatment patterns, safety, and outcomes in CLL and mantle cell lymphoma (MCL).
- Highlights include new comparative efficacy data for BRUKINSA versus fixed-duration regimens based on a network meta-analysis, as well as real-world studies evaluating BTK inhibitor use, treatment disparities, and clinical outcomes across diverse patient populations.

Early phase data includes never-before-presented clinical data from BeiGene's emerging breast cancer pipeline; notable highlights include:

- Preliminary results of the dose escalation study for BG-C9074, a topoisomerase inhibitor antibody-drug conjugate (ADC) targeting the B7-H4 protein, in patients with advanced solid tumors, including breast cancer.

- Early clinical activity for BG-68501, a cyclin-dependent kinase-2 inhibitor (CDK2i), in HR+/HER2- breast cancer patients with prior CDK4/6i exposure, supporting its development as a next-line option for tumors with CDK2 dependency.

Results from the final analysis of the RATIONALE-213 study demonstrate that, using a PET-guided approach, TEVIMBRA plus chemotherapy or chemoradiotherapy showed promising efficacy and a tolerable safety profile in the neoadjuvant setting for resectable esophageal squamous cell carcinoma (ESCC), in both patients who responded and did not respond to preoperative chemotherapy. This adds further evidence to the PD-1 inhibitor's established ability to deliver clinically meaningful efficacy benefits as well as its consistent safety profile.

BeiGene Presentations at 2025 ASCO Annual Meeting

Abstract Title	Presentation Details (CDT)	Lead Author
Hematology		
BRUKINSA		
SEQUOIA 5-year follow-up of Arm C: Frontline zanubrutinib monotherapy in del(17p) patients with treatment-naïve chronic lymphocytic leukemia/small lymphocytic lymphoma	**Rapid Oral Presentation:** 7011 **Session Title:** Hematologic Malignancies - Lymphoma and Chronic Lymphocytic Leukemia **Session Date/Time:** May 31, 2025, 8:00-9:30 AM	C.S. Tam
Combination of zanubrutinib + venetoclax for treatment-naive CLL/SLL: Results from SEQUOIA Arm D	**Rapid Oral Presentation:** 7009 **Session Title:** Hematologic Malignancies - Lymphoma and Chronic Lymphocytic Leukemia **Session Date/Time:** May 31, 2025, 8:00-9:30 AM	M. Shadman
Solid Tumor		
TEVIMBRA		
Tislelizumab (BGB-A317) plus chemotherapy/chemoradiotherapy as positron emission tomography-guided neoadjuvant treatment for resectable esophageal squamous cell carcinoma: RATIONALE-213 final analysis	Poster #: 317 Poster Presentation **Session Title:** Gastrointestinal Cancer - Gastroesophageal, Pancreatic, and Hepatobiliary **Session Date/Time:** May 31, 2025, 9:00 AM-12:00 PM	L. Chen
Final analysis of multicenter, open-label, phase 2 study evaluating the efficacy and safety of tislelizumab in combination with fruquintinib in patients with selected solid tumors	Poster #: 251 Poster Presentation **Session Title:** Developmental Therapeutics – Immunotherapy	K. Lee

	Session Date/Time: June 2, 2025, 1:30 PM-4:30 PM	
Pipeline		
BG-68501 (CDK2i)		
A first-in-human, phase 1a/b, dose-escalation/expansion study of BG-68501, a selective CDK2 inhibitor, as monotherapy or in combination with fulvestrant for patients with HR+/HER2- breast cancer and other advanced solid tumors: First disclosure of clinical data	Poster# 430 Poster Presentation **Session Title:** Development Therapeutics - Molecularly Targeted Agents and Tumor Biology **Session Date/Time:** June 2, 2025, 1:30-4:30 PM	R. Joshi
BG-C9074		
First-in-human study of BG-C9074, a B7-H4-targeting ADC in patients with advanced solid tumors: Preliminary results of the dose-escalation phase	Poster #: 348 Poster Presentation **Session Title:** Development Therapeutics - Molecularly Targeted Agents and Tumor Biology **Session Date/Time:** June 2, 2025, 1:30-4:30 PM	C.A. Perez
BGB-A445 (OX40)		
A phase 1 study of the OX40 agonist, BGB-A445, with or without tislelizumab, an anti-PD-1 monoclonal antibody, in patients with advanced NSCLC, HNSCC or NPC	Poster #: 172 Poster Presentation **Session Title:** Development Therapeutics - Molecularly Targeted Agents and Tumor Biology **Session Date/Time:** June 2, 2025, 1:30-4:30 PM	M. Hee Hong
A phase 2 study of the OX40 agonist BGB-A445, in combination with docetaxel or BGB-15025, an HPK1 inhibitor, in patients with NSCLC pretreated by anti-PD-(L)1 antibodies	Abstract #: e14513 Online Abstract	T. Min Kim
Additional Abstracts		
Clinical Trial Diversity		
Lung cancer enrollment of demographic subgroups in US clinical trial sites	Poster #: 216 Poster Presentation	C. Nigoghossian

	Session Title: Lung Cancer - Non-Small Cell Local-Regional/Small Cell/Other Thoracic Cancers **Session Date/Time:** May 31, 2025, 1:30-4:30 PM	
Integrative Evidence Generation and Health Economics Related to Zanubrutinib		
Preference Survey		
Treatment preferences of patients, caregivers, and physicians in follicular lymphoma: A global discrete-choice experiment study	Poster #: 448 Poster Presentation **Session Title:** Quality Care/Health Services Research **Session Date/Time:** May 31, 2025, 1:30-4:30 PM	M. Smith
Matching-Adjusted Indirect Comparison		
Adverse events of interest of zanubrutinib vs. fixed-duration combination of venetoclax and obinutuzumab in treatment-naïve chronic lymphocytic leukemia	Abstract #: e19028 Online Abstract	W. Aldairy
Efficacy of continuous zanubrutinib vs. fixed duration venetoclax in combination with obinutuzumab in treatment-naïve chronic lymphocytic leukemia: A matching-adjusted indirect comparison	Abstract #: e19027 Online Abstract	T. Munir
Comparative efficacy of zanubrutinib versus fixed-duration acalabrutinib plus venetoclax for first-line treatment of chronic lymphocytic leukemia: A matching-adjusted indirect comparison	Abstract #: e91032 Online Abstract	T. Munir
Network Meta-Analysis		
A network meta-analysis of efficacy of zanubrutinib versus fixed-duration acalabrutinib plus venetoclax in treatment-naïve chronic lymphocytic leukemia	Abstract #: e19031 Online Abstract	M. Shadman
Real-World Evidence		
Real-world comparative effectiveness of first-line Bruton tyrosine kinase inhibitors in patients with chronic lymphocytic leukemia	Abstract #: e23264 Online Abstract	R. Jacobs
Evaluating uptake of targeted agents by race/ethnicity in patients receiving first-line treatment for chronic lymphocytic leukemia	Abstract #: e13741 Online Abstract	A.S. Kittai

Real-world Bruton tyrosine kinase inhibitor use and clinical outcomes among patients with chronic lymphocytic leukemia/small lymphocytic lymphoma	Abstract #: e23271 Online Abstract	J. Hou
Real-world zanubrutinib treatment patterns in chronic lymphocytic leukemia/small lymphocytic lymphoma among US community oncology patients with prior acalabrutinib therapy	Abstract #: e23265 Online Abstract	J. Hou
Real-world zanubrutinib treatment patterns in mantle cell lymphoma among US community oncology patients with prior Bruton tyrosine kinase inhibitor therapy	Abstract #: e23270 Online Abstract	R. Choksi
Risk of hypertension in patients newly diagnosed with chronic lymphocytic leukemia/small lymphocytic lymphoma and treated with covalent Bruton tyrosine kinase inhibitors: A real-world study	Abstract #: e23334 Online Abstract	A.K. Ali
Real-world treatment utilization patterns, discontinuation and healthcare resource utilization of first-line Bruton tyrosine kinase inhibitor therapy in chronic lymphocytic leukemia: Age-related disparity	Abstract #: e19033 Online Abstract	K. Yang
Serious infections in patients with CLL/SLL treated with combination venetoclax and obinutuzumab compared to those treated with zanubrutinib: A real-world study	Abstract #: e19026 Online Abstract	J. Colasurdo
Comparing real-world treatment patterns and outcomes of zanubrutinib and acalabrutinib in CLL/SLL at University of California academic health centers	Abstract #: e23263 Online Abstract	A. Ayati

For additional information about our presence at the 2025 ASCO Annual Meeting, please visit our meeting hub: congress.beonemedicines.com.

About BRUKINSA® (zanubrutinib)
BRUKINSA is an orally available, small molecule inhibitor of Bruton's tyrosine kinase (BTK) designed to deliver complete and sustained inhibition of the BTK protein by optimizing bioavailability, half-life, and selectivity. With differentiated pharmacokinetics compared with other approved BTK inhibitors, BRUKINSA has been demonstrated to inhibit the proliferation of malignant B cells within a number of disease-relevant tissues.

BRUKINSA has the broadest label globally of any BTK inhibitor and is the only BTK inhibitor to provide the flexibility of once or twice daily dosing. Additionally, BRUKINSA is also the only BTK inhibitor to demonstrate superiority to another BTK inhibitor in a Phase 3 study of patients with relapsed / refractory chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL).

The global BRUKINSA clinical development program includes about 7,100 patients enrolled in 30 countries and regions across more than 35 trials. BRUKINSA is approved in more than 75 markets, and more than 200,000 patients have been treated globally.

About TEVIMBRA® (tislelizumab-jsgr)
TEVIMBRA is a uniquely designed humanized immunoglobulin G4 (IgG4) anti-programmed cell death protein 1 (PD-1) monoclonal antibody with high affinity and binding specificity against PD-1. It is designed to minimize binding to Fc-gamma (Fcγ) receptors on macrophages, helping the body's immune cells detect and fight tumors.

TEVIMBRA is the foundational asset of BeiGene's solid tumor portfolio and has shown potential across multiple tumor types and disease settings. The global TEVIMBRA clinical development program includes almost 14,000 patients enrolled to date in 35 countries and regions across 70 trials, including 21 registration-enabling studies. TEVIMBRA is approved in 46 markets, and more than 1.5 million patients have been treated globally.

U.S. Indications and Important Safety Information for BRUKINSA (zanubrutinib)

INDICATIONS

BRUKINSA is a kinase inhibitor indicated for the treatment of adult patients with:

- Chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL).
- Waldenström's macroglobulinemia (WM).
- Mantle cell lymphoma (MCL) who have received at least one prior therapy.
- Relapsed or refractory marginal zone lymphoma (MZL) who have received at least one anti-CD20-based regimen.
- Relapsed or refractory follicular lymphoma (FL), in combination with obinutuzumab, after two or more lines of systemic therapy.

The MCL, MZL and FL indications are approved under accelerated approval based on overall response rate and durability of response. Continued approval for these indications may be contingent upon verification and description of clinical benefit in confirmatory trials.

IMPORTANT SAFETY INFORMATION

Warnings and Precautions

Hemorrhage

Fatal and serious hemorrhage has occurred in patients with hematological malignancies treated with BRUKINSA. Grade 3 or higher hemorrhage including intracranial and gastrointestinal hemorrhage, hematuria, and hemothorax was reported in 3.8% of patients treated with BRUKINSA in clinical trials, with fatalities occurring in 0.2% of patients. Bleeding of any grade, excluding purpura and petechiae, occurred in 32% of patients.

Bleeding has occurred in patients with and without concomitant antiplatelet or anticoagulation therapy. Coadministration 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 before and after surgery depending upon the type of surgery and the risk of bleeding.

Infections

Fatal and serious infections (including bacterial, viral, or fungal infections) and opportunistic infections have occurred in patients with hematological malignancies treated with BRUKINSA. Grade 3 or higher infections occurred in 26% of patients, most commonly pneumonia (7.9%), with fatal infections occurring in 3.2% of patients. Infections due to hepatitis B virus (HBV) reactivation have occurred.

Consider prophylaxis for herpes simplex virus, *pneumocystis jirovecii* 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 (21%), thrombocytopenia (8%) and anemia (8%) based on laboratory measurements, developed in patients treated with BRUKINSA. Grade 4 neutropenia occurred in 10% of patients, and Grade 4 thrombocytopenia occurred in 2.5% of patients.

Monitor complete blood counts regularly during treatment and interrupt treatment, reduce the dose, or discontinue treatment as warranted. Treat using growth factor or transfusions, as needed.

Second Primary Malignancies

Second primary malignancies, including non-skin carcinoma, have occurred in 14% of patients treated with BRUKINSA. The most frequent second primary malignancy was non-melanoma skin cancers (8%), followed by other solid tumors in 7% of the patients (including melanoma in 1% of patients) and hematologic malignancies (0.7%). Advise patients to use sun protection and monitor patients for the development of second primary malignancies.

Cardiac Arrhythmias

Serious cardiac arrhythmias have occurred in patients treated with BRUKINSA. Atrial fibrillation and atrial flutter were reported in 4.4% patients treated with BRUKINSA, including Grade 3 or higher cases in 1.9% of patients. Patients with cardiac risk factors, hypertension, and acute infections may be at increased risk. Grade 3 or higher ventricular arrhythmias were reported in 0.3% of patients.

Monitor for signs and symptoms of cardiac arrhythmias (e.g., palpitations, dizziness, syncope, dyspnea, chest discomfort), manage appropriately, and consider the risks and benefits of continued BRUKINSA treatment.

Hepatotoxicity, Including Drug-Induced Liver Injury

Hepatotoxicity, including severe, life-threatening, and potentially fatal cases of drug-induced liver injury (DILI), has occurred in patients treated with Bruton tyrosine kinase inhibitors, including BRUKINSA.

Evaluate bilirubin and transaminases at baseline and throughout treatment with BRUKINSA. For patients who develop abnormal liver tests after BRUKINSA, monitor more frequently for liver test abnormalities and clinical signs and symptoms of hepatic toxicity. If DILI is suspected, withhold BRUKINSA. Upon confirmation of DILI, discontinue BRUKINSA.

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 1 week after the last dose. Advise men to avoid fathering a child during treatment and for 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 (≥30%), including laboratory abnormalities, in patients who received BRUKINSA (N=1729) are decreased neutrophil count (51%), decreased platelet count (41%), upper respiratory tract infection (38%), hemorrhage (32%), and musculoskeletal pain (31%).

Drug Interactions

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

CYP3A Inducers: Avoid coadministration with strong or moderate CYP3A inducers. Dose adjustment may be recommended with moderate CYP3A inducers.

Specific Populations

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

Please see full U.S. Prescribing Information including U.S. Patient Information.

U.S. Indication and Important Safety Information for TEVIMBRA (tislelizumab-jsgr) injection

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

Severe and Fatal Immune-Mediated Adverse Reactions

TEVIMBRA is a monoclonal antibody that belongs to a class of drugs that bind to either the programmed death receptor-1 (PD-1) or PD-ligand 1 (PD-L1), blocking the PD-1/PD-L1 pathway, thereby removing inhibition of the immune response, potentially breaking peripheral tolerance and inducing immune-mediated adverse reactions.

Immune-mediated adverse reactions, which may be severe or fatal, can occur in any organ system or tissue. Immune-mediated adverse reactions can occur at any time after starting treatment with a PD-1/PD-L1 blocking antibody. While immune-mediated adverse reactions usually manifest during treatment with PD-1/PD-L1 blocking antibodies, immune-mediated adverse reactions can also manifest after discontinuation of PD-1/PD-L1 blocking antibodies. Important immune-mediated adverse reactions listed here may not include all possible severe and fatal immune-mediated reactions.

Early identification and management of immune-mediated adverse reactions are essential to ensure safe use of PD-1/PD-L1 blocking antibodies. Monitor patients closely for symptoms and signs that may be clinical manifestations of underlying immune-mediated adverse reactions. Evaluate liver enzymes, creatinine, and thyroid function at baseline and periodically during treatment. In cases of suspected immune-mediated adverse reactions, initiate appropriate workup to exclude alternative etiologies, including infection. Institute medical management promptly, including specialty consultation as appropriate.

Withhold or permanently discontinue TEVIMBRA depending on severity. In general, if TEVIMBRA requires interruption or discontinuation, administer systemic corticosteroid therapy (1 to 2 mg/kg/day prednisone or equivalent) until improvement to Grade 1 or less. Upon improvement to Grade 1 or less, initiate corticosteroid taper and continue to taper over at least 1 month. Consider administration of other systemic immunosuppressants in patients whose immune-mediated adverse reactions are not controlled with corticosteroids.

Immune-Mediated Pneumonitis

TEVIMBRA can cause immune-mediated pneumonitis, which can be fatal. In patients treated with other PD-1/PD-L1 blocking antibodies, the incidence of pneumonitis is higher in patients who have received prior thoracic radiation.

Immune-mediated pneumonitis occurred in 4.9% (96/1972) of patients receiving TEVIMBRA, including fatal (0.1%), Grade 4 (0.3%), Grade 3 (1.6%) and Grade 2 (1.9%) adverse reactions. Pneumonitis led to permanent discontinuation of TEVIMBRA in 38 (1.9%) patients and withholding of TEVIMBRA in 32 (1.6%) patients.

Seventy-four (77.1%) of the 96 patients received systemic corticosteroids. Sixty-five (67.7%) of the 96 patients received high-dose systemic corticosteroids. Immune-mediated pneumonitis resolved in 50% of the 96 patients. Of the 32 patients in whom TEVIMBRA was withheld for pneumonitis, 20 (62.5%) reinitiated TEVIMBRA after symptom improvement; of these, 2 (10%) patients had recurrence of pneumonitis.

Immune-Mediated Colitis

TEVIMBRA can cause immune-mediated colitis, which can be fatal. Cytomegalovirus (CMV) infection/reactivation has been reported in patients with corticosteroid-refractory immune-mediated colitis treated with PD-1/PD-L1 blocking antibodies. In cases of corticosteroid-refractory colitis, consider repeating infectious workup to exclude alternative etiologies.

Immune-mediated colitis occurred in 0.8% (16/1972) of patients receiving TEVIMBRA, including Grade 3 (0.3%) and Grade 2 (0.4%) adverse reactions. Colitis led to permanent discontinuation of TEVIMBRA in 4 (0.2%) patients and withholding of TEVIMBRA in 5 (0.3%) patients. Twelve (75%) of the 16 patients received systemic corticosteroids. Eight (50%) of the 16 patients received high-dose systemic corticosteroids. Two (12.5%) of the 16 patients received immunosuppressive treatment. Immune-mediated

colitis resolved in 93.8% of the 16 patients. All 5 patients in whom TEVIMBRA was withheld for colitis reinitiated TEVIMBRA after symptom improvement; of these, none of the patients had recurrence of colitis.

Immune-Mediated Hepatitis

TEVIMBRA can cause immune-mediated hepatitis, which can be fatal.

Immune-mediated hepatitis occurred in 1.2% (24/1972) of patients receiving TEVIMBRA, including fatal (0.1%), Grade 4 (0.2%), Grade 3 (0.5%) and Grade 2 (0.4%) adverse reactions. Immune-mediated hepatitis led to permanent discontinuation in 3 (0.2%) patients and withholding of TEVIMBRA in 13 (0.7%) patients. Eighteen (75%) of the 24 patients received systemic corticosteroids. Thirteen (54.2%) of the 24 patients received high-dose systemic corticosteroids. Two patients (8.3%) of the 24 patients received immunosuppressive treatment. Immune-mediated hepatitis resolved in 70.8% of the 24 patients. Of the 13 patients in whom TEVIMBRA was withheld for hepatitis, 7 (53.8%) reinitiated TEVIMBRA after symptom improvement; of these, none of the patients had recurrence of hepatitis.

Immune-Mediated Endocrinopathies

Adrenal Insufficiency

TEVIMBRA can cause immune-mediated adrenal insufficiency. For Grade 2 or higher adrenal insufficiency, initiate symptomatic treatment, including hormone replacement as clinically indicated. Withhold TEVIMBRA depending on severity.

Immune-mediated adrenal insufficiency occurred in 0.4% (8/1972) of patients receiving TEVIMBRA, including Grade 4 (0.1%), Grade 3 (0.1%) and Grade 2 (0.3%) adverse reactions. Adrenal insufficiency did not lead to permanent discontinuation of TEVIMBRA. TEVIMBRA was withheld in 7 (0.4%) patients. All 8 patients received systemic corticosteroids. Three (37.5%) of the 8 patients received high-dose systemic corticosteroids. Adrenal insufficiency resolved in 25% of the 8 patients. Of the 7 patients in whom TEVIMBRA was withheld for adrenal insufficiency, 5 (71.4%) reinitiated TEVIMBRA after symptom improvement; of these, none of the patients had recurrence of adrenal insufficiency.

Hypophysitis

TEVIMBRA can cause immune-mediated hypophysitis. Hypophysitis can present with acute symptoms associated with mass effect such as headache, photophobia, or visual field defects. Hypophysitis can cause hypopituitarism. Initiate hormone replacement as clinically indicated. Withhold or permanently discontinue TEVIMBRA depending on severity.

Hypophysitis/hypopituitarism occurred in 0.2% (4/1972) of patients receiving TEVIMBRA, including a Grade 2 (0.2%) adverse reaction. No TEVIMBRA treatment discontinuation was required, while treatment was withheld in 1 (0.1%) patient. Three (75%) of the 4 patients received systemic corticosteroids. One (25%) of the 4 patients received high-dose systemic corticosteroids. Hypophysitis/hypopituitarism did not resolve in the 4 patients. For the 1 patient where TEVIMBRA was withheld for hypophysitis/hypopituitarism, there was no recurrence of hypophysitis/hypopituitarism.

Thyroid Disorders

TEVIMBRA can cause immune-mediated thyroid disorders. Thyroiditis can present with or without endocrinopathy. Hypothyroidism can follow hyperthyroidism. Initiate hormone replacement for

hypothyroidism or institute medical management of hyperthyroidism as clinically indicated. Withhold or permanently discontinue TEVIMBRA depending on severity.

Thyroiditis: Immune-mediated thyroiditis occurred in 1.2% (24/1972) of patients receiving TEVIMBRA, including Grade 2 (0.5%) adverse reactions. Thyroiditis did not lead to permanent discontinuation of TEVIMBRA. TEVIMBRA was withheld in 3 (0.2%) patients. Two (8.3%) of the 24 patients received systemic corticosteroids. Thyroiditis resolved in 41.7% of the 24 patients. All three patients in whom TEVIMBRA was withheld for thyroiditis reinitiated TEVIMBRA after symptom improvement; of these, none of the patients had recurrence of thyroiditis.

Hyperthyroidism: Immune-mediated hyperthyroidism occurred in 4.8% (95/1972) of patients receiving TEVIMBRA, including Grade 3 (0.1%) and Grade 2 (0.9%) adverse reactions. Hyperthyroidism led to the permanent discontinuation of TEVIMBRA in 1 (0.1%) patient and withholding of TEVIMBRA in 4 (0.2%) patients. One (1.1%) of the 95 patients received systemic corticosteroids. Hyperthyroidism resolved in 75.8% of the 95 patients. Of the 4 patients in whom TEVIMBRA was withheld for hyperthyroidism, 3 (75%) reinitiated TEVIMBRA after symptom improvement; of these, none of the patients had recurrence of hyperthyroidism.

Hypothyroidism: Immune-mediated hypothyroidism occurred in 12.7% (250/1972) of patients receiving TEVIMBRA, including Grade 4 (0.1%) and Grade 2 (6.8%) adverse reactions. TEVIMBRA was not permanently discontinued in any patient, while treatment was withheld in 7 (0.4%) patients. Two (0.8%) of the 250 patients received systemic corticosteroids and 158 patients (63.2%) received hormone replacement therapy. Hypothyroidism resolved in 31.6% of the 250 patients. The majority (51.6%) of patients with hypothyroidism required long-term thyroid hormone replacement. Of the 7 patients in whom TEVIMBRA was withheld for hypothyroidism, 6 (85.7%) reinitiated TEVIMBRA after symptom improvement; of these, none of the patients had recurrence of hypothyroidism.

Type 1 Diabetes Mellitus, which can present with Diabetic Ketoacidosis

Diabetes mellitus has been reported with PD-1/PD-L1 blocking antibodies. Monitor patients for hyperglycemia or other signs and symptoms of diabetes. Initiate treatment with insulin as clinically indicated. Withhold or permanently discontinue TEVIMBRA depending on severity.

Diabetes mellitus occurred in 0.9% (18/1972) of patients receiving TEVIMBRA, including Grade 4 (0.1%), Grade 3 (0.4%) and Grade 2 (0.4%) adverse reactions. TEVIMBRA was permanently discontinued in 3 (0.2%) patients and TEVIMBRA treatment was withheld in 3 (0.2%) patients. Twelve (66.7%) patients received insulin therapy for diabetes mellitus. Diabetes mellitus resolved in 27.8% of the 18 patients. Of the 3 patients in whom TEVIMBRA was withheld for diabetes mellitus, none of the patients reinitiated TEVIMBRA after symptom improvement.

Immune-Mediated Nephritis with Renal Dysfunction

TEVIMBRA can cause immune-mediated nephritis, which can be fatal.

Immune-mediated nephritis with renal dysfunction occurred in 0.3% (5/1972) of patients receiving TEVIMBRA, including Grade 3 (0.1%) and Grade 2 (0.2%) adverse reactions. TEVIMBRA was permanently discontinued in 1 (0.1%) patient and treatment was withheld in 3 (0.2%) patients. Three (60%) of the 5 patients received systemic corticosteroids. All 3 (60%) of the 5 patients received high-dose systemic corticosteroids. Nephritis with renal dysfunction resolved in 40.0% of the 5 patients. Of the 3 patients in whom TEVIMBRA was withheld for nephritis, 2 (66.7%) reinitiated TEVIMBRA after symptom improvement and one (50%) patient had recurrence of nephritis.

Immune-Mediated Dermatologic Adverse Reactions

TEVIMBRA can cause immune-mediated rash or dermatitis. Cases of severe cutaneous adverse reactions (SCARs), including exfoliative dermatitis, Stevens-Johnson Syndrome (SJS), and toxic epidermal necrolysis (TEN), have been reported, some with fatal outcome. Topical emollients and/or topical corticosteroids may be adequate to treat mild to moderate non-exfoliative rashes. Withhold or permanently discontinue TEVIMBRA depending on severity.

Immune-mediated dermatologic adverse reactions occurred in 15.3% (301/1972) of patients receiving TEVIMBRA, including Grade 4 (0.1%), Grade 3 (0.9%) and Grade 2 (3.5%) adverse reactions. Dermatologic adverse reactions led to permanent discontinuation of TEVIMBRA in 2 (0.1%) patients and withholding of TEVIMBRA in 18 (0.9%) patients. Thirty (10.0%) of the 301 patients received systemic corticosteroids. Thirteen (4.3%) of the 301 patients received high-dose systemic corticosteroids. Immune-mediated skin reactions resolved in 190 (63.1%) of the 301 patients. Of the 18 patients in whom TEVIMBRA was withheld for dermatologic adverse reactions, 15 (83.3%) reinitiated TEVIMBRA after symptom improvement; of these, 1 (6.7%) patient had recurrence of immune-mediated dermatologic adverse reactions.

Other Immune-Mediated Adverse Reactions

The following clinically significant immune-mediated adverse reactions occurred at an incidence of less than 1% each in 1972 patients who received TEVIMBRA: myositis, myocarditis, arthritis, polymyalgia rheumatica, and pericarditis.

The following additional clinically significant immune-mediated adverse reactions have been reported with other PD-1/PD-L1 blocking antibodies, including severe or fatal cases.

Cardiac/Vascular: Vasculitis.

Nervous System: Meningitis, encephalitis, myelitis and demyelination, myasthenic syndrome/myasthenia gravis (including exacerbation), Guillain-Barré syndrome, nerve paresis, autoimmune neuropathy.
Ocular: Uveitis, iritis, and other ocular inflammatory toxicities can occur. Some cases can be associated with retinal detachment. Various grades of visual impairment, including blindness, can occur. If uveitis occurs in combination with other immune-mediated adverse reactions, consider a Vogt-Koyanagi-Harada-like syndrome, as this may require treatment with systemic steroids to reduce the risk of permanent vision loss.

Gastrointestinal: Pancreatitis including increases in serum amylase and lipase levels, gastritis, duodenitis.
Musculoskeletal and Connective Tissue: Polymyositis, rhabdomyolysis and associated sequelae including renal failure.

Endocrine: Hypoparathyroidism.

Other (Hematologic/Immune): Hemolytic anemia, aplastic anemia, hemophagocytic lymphohistiocytosis, systemic inflammatory response syndrome, histiocytic necrotizing lymphadenitis (Kikuchi lymphadenitis), sarcoidosis, immune thrombocytopenic purpura, solid organ transplant rejection, other transplant (including corneal graft) rejection.

Infusion-Related Reactions

TEVIMBRA can cause severe or life-threatening infusion-related reactions. Infusion-related reactions occurred in 5% (99/1972) patients receiving TEVIMBRA, including Grade 3 or higher (0.2%) reactions. Monitor patients for signs and symptoms of infusion-related reactions.

Slow the rate of infusion for mild (Grade 1) and interrupt the infusion for moderate (Grade 2) infusion-related reactions. For severe (Grade 3) or life-threatening (Grade 4) infusion-related reactions, stop infusion and permanently discontinue TEVIMBRA.

Complications of Allogeneic HSCT

Fatal and other serious complications can occur in patients who receive allogeneic hematopoietic stem cell transplantation (HSCT) before or after being treated with a PD-1/PD-L1 blocking antibody. Transplant-related complications include hyperacute graft-versus-host disease (GVHD), acute GVHD, chronic GVHD, hepatic veno-occlusive disease after reduced intensity conditioning, and steroid-requiring febrile syndrome (without an identified infectious cause). These complications may occur despite intervening therapy between PD-1/PD-L1 blockade and allogeneic HSCT.

Follow patients closely for evidence of transplant-related complications and intervene promptly. Consider the benefit versus risks of treatment with a PD-1/PD-L1 blocking antibody prior to or after an allogeneic HSCT.

Embryo-Fetal Toxicity

Based on its mechanism of action, TEVIMBRA can cause fetal harm when administered to a pregnant woman. Animal studies have demonstrated that inhibition of the PD-1/PD-L1 pathway can lead to increased risk of immune-mediated rejection of the developing fetus resulting in fetal death. Advise pregnant women of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment with TEVIMBRA and for 4 months after the last dose.

ADVERSE REACTIONS

First-line Treatment of Unresectable Advanced or Metastatic Esophageal Carcinoma (ESCC)
Permanent discontinuation of TEVIMBRA due to adverse reactions occurred in 13% of patients. The adverse reaction which resulted in discontinuation in ≥2% of patients was pneumonitis (2.2%).

Dosage interruptions of TEVIMBRA due to adverse reactions occurred in 52% of patients. Adverse reactions which required dosage interruption in ≥2% of patients were neutrophil count decreased (7%), fatigue (6%), pneumonia (6%), anemia (4.3%), neutropenia (4.3%), white blood cell count decreased (4.3%), rash (3.7%), dysphagia (2.8%), platelet count decreased (2.8%), pyrexia (2.8%), and diarrhea (2.2%).

The most common (≥20%) adverse reactions, including laboratory abnormalities were decreased neutrophil count, decreased sodium, increased glucose, anemia, fatigue, decreased appetite, increased AST, decreased potassium, increased serum creatinine, decreased calcium, increased ALT, diarrhea, stomatitis, and vomiting.

Previously Treated Unresectable Advanced or Metastatic ESCC

Permanent discontinuation of TEVIMBRA due to an adverse reaction occurred in 19% of patients. Adverse reactions which resulted in permanent discontinuation in ≥1% of patients were hemorrhage, pneumonitis (including pneumonitis and immune-mediated pneumonitis), and pneumonia.

Dosage interruptions of TEVIMBRA due to an adverse reaction occurred in 23% of patients. Adverse reactions which required dosage interruptions in ≥2% of patients were pneumonia, pneumonitis, and fatigue.

The most common (≥20%) adverse reactions, including laboratory abnormalities, were increased glucose, decreased hemoglobin, decreased lymphocytes, decreased sodium, decreased albumin, increased alkaline phosphatase, anemia, fatigue, increased AST, musculoskeletal pain, decreased weight, increased ALT, and cough.

Treatment of Previously Untreated Unresectable or Metastatic Gastric or Gastroesophageal Junction Adenocarcinoma (G/GEJ)

Permanent discontinuation of TEVIMBRA due to an adverse drug reaction occurred in 16% of patients. Adverse drug reactions which resulted in permanent discontinuation in ≥1% of patients were death, fatigue, and pneumonitis.

Dosage interruption of TEVIMBRA in the TEVIMBRA plus chemotherapy arm due to an adverse drug reaction occurred in 49% of patients. Adverse drug reactions which required dosage modifications in ≥2% of patients were, platelet count decreased (12%), neutrophil count decreased (10%), neutropenia (6%), white blood cell count decreased (6%), increased AST (4.8%), increased ALT (3.8%), increased blood bilirubin (3%), COVID-19 (3%), thrombocytopenia (2.8%), leukopenia (2.6%), pneumonitis (2.2%), and pneumonia (2%).

The most common (≥20%) adverse reactions, including laboratory abnormalities, for TEVIMBRA in combination with chemotherapy were nausea, fatigue, decreased appetite, anemia, peripheral sensory neuropathy, vomiting, decreased platelet count, decreased neutrophil count, increased aspartate aminotransferase, diarrhea, abdominal pain, increased alanine aminotransferase, decreased white blood cell count, decreased weight, and pyrexia.

INDICATIONS

TEVIMBRA is a programmed death receptor-1 (PD-1)-blocking antibody indicated for:

Esophageal Cancer

- in combination with platinum-containing chemotherapy for the first-line treatment of adults with unresectable or metastatic esophageal squamous cell carcinoma (ESCC) whose tumors express PD-L1 (≥1).
- as a single-agent, for the treatment of adults with unresectable or metastatic ESCC after prior systemic chemotherapy that did not include a PD-(L)1 inhibitor.

Gastric Cancer

- in combination with platinum and fluoropyrimidine-based chemotherapy for the first-line treatment of adults with unresectable or metastatic HER2-negative gastric or gastroesophageal junction adenocarcinoma whose tumors express PD-L1 (≥1).

Please see full U.S. Prescribing Information including the U.S. Medication Guide.

About BeiGene

BeiGene, which will change its name to BeOne Medicines Ltd., is a global oncology company that is discovering and developing innovative treatments that are more affordable and accessible to cancer patients worldwide. With a broad portfolio, we are expediting development of our diverse pipeline of novel therapeutics through our internal capabilities and collaborations. We are committed to radically improving access to medicines for far more patients who need them. Our growing global team of more

than 11,000 colleagues spans six continents. To learn more about BeiGene, please visit www.beigene.com.

Forward-Looking Statement
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 BeiGene's ability to provide innovative medicines to as many patients as possible worldwide; the depth and momentum of BeiGene's oncology portfolio; and BeiGene's plans, commitments, aspirations, and goals under the heading "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, commercialization, 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 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. To access BeiGene media resources, please visit our **News & Media** site.

Investor Contact
Liza Heapes
+1 857-302-5663
ir@beigene.com

Media Contact
Kim Bencker
+1 610-256-8932
media@beigene.com

###