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

INSIDE INFORMATION

BeiGene Receives FDA Approval for TEVIMBRA[®] (tislelizumab) for the Treatment of Advanced or Metastatic Esophageal Squamous Cell Carcinoma After Prior Chemotherapy

This announcement is issued pursuant to Rule 13.09 of the Rules Governing the Listing of the Securities on The Stock Exchange of Hong Kong Limited (the “**Listing Rules**”) and under Part XIVA of the Securities and Futures Ordinance (Cap. 571).

On March 14, 2024 (U.S. Eastern Time), BeiGene, Ltd. (the “**Company**” or “**BeiGene**”) announced that the U.S. Food and Drug Administration (FDA) has approved TEVIMBRA[®] (tislelizumab) as monotherapy for the treatment of adult patients with unresectable or metastatic esophageal squamous cell carcinoma (ESCC) after prior systemic chemotherapy that did not include a PD-(L)1 inhibitor.

Attached hereto as Schedule 1 is the full text of the press release issued by the Company on March 14, 2024 announcing the above-described business update.

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 BeiGene’s ability to bring TEVIMBRA to more patients around the world; the future significance of TEVIMBRA in BeiGene’s solid tumor development program; the potential of TEVIMBRA to be an important treatment for ESCC; 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; BeiGene’s 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 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 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.

The Company’s shareholders and potential investors are advised not to place undue reliance on this announcement and to exercise caution in dealing in securities in the Company.

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

Hong Kong, March 15, 2024

As of the date of this announcement, the Board of Directors of the Company consists of Mr. John V. Oyler as Chairman and Executive Director, Dr. Xiaodong Wang as Non-executive Director, and Dr. Olivier Brandicourt, Dr. Margaret Han Dugan, Mr. Donald W. Glazer, Mr. Michael Goller, Mr. Anthony C. Hooper, Mr. Ranjeev Krishana, Dr. Alessandro Riva, Dr. Corazon (Corsee) D. Sanders and Mr. Qingqing Yi as Independent Non-executive Directors.

SCHEDULE 1

BeiGene Receives FDA Approval for TEVIMBRA® for the Treatment of Advanced or Metastatic Esophageal Squamous Cell Carcinoma After Prior Chemotherapy

Results from the global, Phase 3 RATIONALE 302 trial showed TEVIMBRA prolonged the survival of patients who received prior systemic treatment compared to chemotherapy

Approval represents the first indication in the U.S. for TEVIMBRA

BASEL, Switzerland & BEIJING & CAMBRIDGE, Mass. – (BUSINESS WIRE) – March 14, 2024 – BeiGene, Ltd. (NASDAQ: BGNE; HKEX: 06160; SSE: 688235), a global oncology company, today announced that the U.S. Food and Drug Administration (FDA) has approved TEVIMBRA® (tislelizumab-jsgr) as monotherapy for the treatment of adult patients with unresectable or metastatic esophageal squamous cell carcinoma (ESCC) after prior systemic chemotherapy that did not include a PD-(L)1 inhibitor. TEVIMBRA will be available in the U.S. in the second half of 2024.

“Today’s FDA approval of TEVIMBRA for patients with ESCC who have previously received chemotherapy, along with its ongoing review of our BLA for first-line ESCC patients, represents a significant step in our commitment to bringing this therapy to more patients around the world,” said Mark Lanasa, M.D., Ph.D., Chief Medical Officer, Solid Tumors at BeiGene. “As BeiGene’s first drug candidate produced through our immuno-oncology program and second approved medicine in the U.S., TEVIMBRA is poised to be a critical pillar of our solid tumor development program, which spans more than 17 registration-enabling clinical trials in more than 30 countries across regions globally.”

The approval is based on the RATIONALE 302 trial, which met its primary endpoint in the intention-to-treat (ITT) population with a statistically significant and clinically meaningful survival benefit for TEVIMBRA compared with chemotherapy. In the ITT population, the median overall survival (OS) in the TEVIMBRA arm was 8.6 months (95% CI: 7.5, 10.4) compared to 6.3 months (95% CI: 5.3, 7.0) in the chemotherapy arm ($p=0.0001$; hazard ratio [HR]=0.70 [95% CI: 0.57, 0.85]). The safety profile of TEVIMBRA was favorable over chemotherapy.ⁱ The most common ($\geq 20\%$) adverse reactions for TEVIMBRA, 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.ⁱ

“Patients diagnosed with advanced or metastasized ESCC, the most common histologic subtype of esophageal cancer, often progress following initial therapy and are in need of new options,” Syma Iqbal, M.D., Associate Professor of Clinical Medicine, Section Chief Gastrointestinal Oncology, Division of Medical Oncology and Cancer Physician in Chief, Norris Comprehensive Cancer Center, Keck School of Medicine, University of Southern California. “The RATIONALE 302 trial showed that patients with previously treated ESCC who received TEVIMBRA saw a clinically meaningful survival benefit, highlighting its potential as an important treatment option for these patients.”

Tislelizumab received approval by the European Commission for advanced or metastatic ESCC after prior chemotherapy in 2023 and a positive opinion by the Committee for Medicinal Products for Human Use of the European Medicines Agency (EMA) in February 2024 as a treatment for non-small cell lung cancer across three indications.

The FDA is also reviewing Biologics License Applications (BLAs) for tislelizumab as a first-line treatment for patients with unresectable, recurrent, locally advanced, or metastatic ESCC and patients with locally advanced unresectable or metastatic gastric or gastroesophageal junction (G/GEJ) adenocarcinoma. The target action dates are July and December 2024, respectively.

BeiGene has launched more than 17 potentially registration-enabling trials with TEVIMBRA, of which 11 Phase 3 randomized trials and four Phase 2 trials have already had positive readouts. Through these trials, TEVIMBRA has demonstrated its potential to deliver clinically meaningful improvements in survival benefits and quality of life for hundreds of thousands of cancer patients across a range of tumor types – in many cases, regardless of PD-(L)1 status – both as monotherapy and in combination with other regimens. More than 900,000 patients have been prescribed TEVIMBRA globally to date.

About RATIONALE 302

RATIONALE 302 is a global, randomized, open-label, Phase 3 study ([NCT03430843](#)) designed to investigate the efficacy and safety of TEVIMBRA when compared with investigator's choice of chemotherapy as a second-line treatment for patients with unresectable, locally advanced or metastatic ESCC. The study randomized 512 patients from 132 research sites in 11 countries in Europe, Asia and North America.

About ESCC

Globally, esophageal cancer (EC) is the sixth most common cause of cancer-related deaths, and ESCC is the most common histologic subtype, accounting for nearly 90% of ECs.ⁱⁱ An estimated 957,000 new EC cases are projected in 2040, an increase of nearly 60% from 2020, underscoring the need for additional effective treatments.ⁱⁱ EC is a rapidly fatal disease, and more than two-thirds of patients have advanced or metastatic disease at the time of diagnosis, with an expected five-year survival rate of less than 6% for those with distant metastases.ⁱⁱⁱ

About TEVIMBRA® (tislelizumab-jsgr)

Tislelizumab 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 to aid the body's immune cells to detect and fight tumors.

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

INDICATION

TEVIMBRA (tislelizumab-jsgr), as a single agent, is indicated for the treatment of adult patients with unresectable or metastatic esophageal squamous cell carcinoma after prior systemic chemotherapy that did not include a PD-(L)1 inhibitor.

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 3.8% (75/1972) of patients receiving TEVIMBRA, including fatal (0.2%), Grade 4 (0.3%), Grade 3 (1.4%), and Grade 2 (1.7%) adverse reactions. Pneumonitis led to permanent discontinuation of TEVIMBRA in 35 (1.8%) patients and withholding of TEVIMBRA in 27 (1.4%) patients.

Systemic corticosteroids were required in all patients with pneumonitis. Immune-mediated pneumonitis resolved in 47% of the 75 patients. Of the 27 patients in whom TEVIMBRA was withheld for pneumonitis, 18 reinitiated TEVIMBRA after symptom improvement; of these, 3 (17%) 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 0.9% (17/1972) of patients receiving TEVIMBRA, including Grade 3 (0.4%), and Grade 2 (0.5%) adverse reactions. Colitis led to permanent discontinuation of TEVIMBRA in 2 (0.1%) patients and withholding of TEVIMBRA in 10 (0.5%) patients. All 17 patients received systemic corticosteroids. Twelve (71%) of the 17 patients received high-dose systemic corticosteroids. Two (12%) of the 17 patients received immunosuppressive treatment. Immune-mediated colitis resolved in 88% of the 17 patients. Of the 10 patients in whom TEVIMBRA was withheld for colitis, 8 reinitiated TEVIMBRA after symptom improvement; of these, 1 (13%) patient had recurrence of colitis.

Immune-Mediated Hepatitis

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

Immune-mediated hepatitis occurred in 1.7% (34/1972) of patients receiving TEVIMBRA, including fatal (0.1%), Grade 4 (0.1%), Grade 3 (1%), and Grade 2 (0.6%) adverse reactions. Immune-mediated hepatitis led to permanent discontinuation in 9 (0.5%) patients and withholding of TEVIMBRA in 20 (1%) patients. All patients received systemic corticosteroids. Twenty-nine (85%) of the 34 patients received high-dose systemic corticosteroids. One patient (2.9%) of the 34 patients received immunosuppressive treatment. Immune-mediated hepatitis resolved in 59% of the 34 patients. Of the 20 patients in whom TEVIMBRA was withheld for hepatitis, 12 reinitiated TEVIMBRA after symptom improvement; of these, 2 (17%) 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 0.3% (6/1972) of patients receiving TEVIMBRA, including Grade 4 (0.1%), Grade 3 (0.1%), and Grade 2 (0.2%) adverse reactions. Adrenal insufficiency did not lead to permanent discontinuation of TEVIMBRA. TEVIMBRA was withheld in 5 out of the 6 patients. All 6 patients received systemic corticosteroids. Two (33%) of the 6 patients received high-dose systemic corticosteroids. Adrenal insufficiency resolved in 17% of the 6 patients.

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 0.1% (1/1972) of patients receiving TEVIMBRA, including a Grade 2 (0.1%) adverse reaction. No TEVIMBRA treatment discontinuation or withholding was required.

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 0.4% (7/1972) of patients receiving TEVIMBRA, including Grade 2 (0.3%) adverse reactions. Thyroiditis did not lead to permanent discontinuation of TEVIMBRA. TEVIMBRA was withheld in 1 (0.1%) patient. One (14%) of the 7 patients received systemic corticosteroids. Thyroiditis resolved in 29% of the 7 patients.

Hyperthyroidism: Immune-mediated hyperthyroidism occurred in 0.6% (12/1972) of patients receiving TEVIMBRA, including Grade 3 (0.1%), and Grade 2 (0.5%) adverse reactions. Hyperthyroidism led to the permanent discontinuation of TEVIMBRA in 1 (0.1%) patient and withholding of TEVIMBRA in 1 (0.1%) patient. One (8%) of the 12 patients received systemic corticosteroids. Hyperthyroidism resolved in 92% of the 12 patients.

Hypothyroidism: Immune-mediated hypothyroidism occurred in 7% (132/1972) of patients receiving TEVIMBRA, including Grade 4 (0.1%) and Grade 2 (5%) adverse reactions. TEVIMBRA was not permanently discontinued in any patient, while treatment was withheld in 6 (0.3%) patients. Two (1.5%) of the 132 patients received systemic corticosteroids. All 132 patients received hormone replacement therapy. Hypothyroidism resolved in 27% of the 132 patients. The majority (86%) of patients with hypothyroidism required long-term thyroid hormone replacement.

Type 1 Diabetes Mellitus, which can present with Diabetic Ketoacidosis

Type 1 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.

Immune-Mediated Nephritis with Renal Dysfunction

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

Immune-mediated nephritis with renal dysfunction occurred in 0.4% (7/1972) of patients receiving TEVIMBRA, including Grade 4 (0.1%), Grade 3 (0.1%), and Grade 2 (0.2%) adverse reactions. TEVIMBRA was permanently discontinued in 3 (0.2%) patients and treatment was withheld in 3 (0.2%) patients. All patients received systemic corticosteroids. Nephritis with renal dysfunction resolved in 57% of the 7 patients. Of the 3 patients in whom TEVIMBRA was withheld for nephritis, 2 reinitiated TEVIMBRA after symptom improvement and one 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 1.2% (24/1972) of patients receiving TEVIMBRA, including Grade 4 (0.2%), Grade 3 (0.4%), and Grade 2 (0.4%) adverse reactions. Dermatologic adverse reactions led to permanent discontinuation of TEVIMBRA in 3 (0.2%) patients and withholding of TEVIMBRA in 9 (0.5%) patients. Twenty-three (96%) of the 24 patients received systemic corticosteroids. Immune-mediated skin reactions resolved in 58% of the 24 patients. Of the 9 patients in whom TEVIMBRA was withheld for dermatologic adverse reactions, 8 reinitiated TEVIMBRA after symptom improvement; of these, 2 (25%) patients had recurrence of immune-mediated rash.

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-Barre 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 4.2% (83/1972) patients receiving TEVIMBRA, including Grade 3 or higher (0.3%) 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 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

Permanent discontinuation of TEVIMBRA due to an adverse reaction occurred in 19% of patients. Adverse reactions which resulted in permanent discontinuation in $\geq 1\%$ 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 $\geq 2\%$ of patients were pneumonia, pneumonitis, and fatigue.

The most common ($\geq 20\%$) 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.

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

About BeiGene

BeiGene 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 10,000 colleagues spans five continents, with administrative offices in Basel, Beijing, and Cambridge, U.S. To learn more about BeiGene, please visit www.beigene.com and follow us on [LinkedIn](#) and [X](#) (formerly known as Twitter).

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 BeiGene's ability to bring TEVIMBRA to more patients around the world; the future significance of TEVIMBRA in BeiGene's solid tumor development program; the potential of TEVIMBRA to be an important treatment for ESCC; 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.

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- ⁱⁱ Morgan E, et al. The Global Landscape of Esophageal Squamous Cell Carcinoma and Esophageal Adenocarcinoma Incidence and Mortality in 2020 and Projections to 2040: New Estimates From GLOBOCAN 2020. *Gastroenterology*. 2022 Sep;163(3):649-658.e2. doi: 10.1053/j.gastro.2022.05.054. Epub 2022 Jun 4. PMID: 35671803.
- ⁱⁱⁱ National Cancer Institute. Cancer stat facts: esophageal cancer. <https://seer.cancer.gov/statfacts/html/esoph.html>.