BeiGene

TEVIMBRA® (tislelizumab-jsgr) Injection, for intravenous use 10 mg/mL

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FOR MEDICAL PRESS ONLY

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What is TEVIMBRA?

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.

TEVIMBRA is the first medicine to emerge from BeiGene's immuno-oncology biologics program.

BeiGene has launched more than 17 potentially registration-enabling clinical trials for TEVIMBRA.

TEVIMBRA U.S. Approvals

TEVIMBRA is approved in the United States (U.S.) 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.[i]

TEVIMBRA Global Approvals

TEVIMBRA is approved by the European Commission as monotherapy for the treatment of adult patients with unresectable, locally advanced, or metastatic ESCC after prior platinum-based chemotherapy. In China, TEVIMBRA is approved across 12 different indications.

Regulatory Filings

U.S.

The U.S. Food and Drug Administration is also reviewing Biologics License Applications for TEVIMBRA 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.

Europe

The Committee for Medicinal Products for Human Use of the European Medicines Agency issued a positive opinion for TEVIMBRA for the treatment of patients with non-small cell lung cancer (NSCLC) across three indications.

Global

Regulatory submissions for TEVIMBRA are also under review by authorities in the U.K., Australia, China, New Zealand, Brazil, Korea, Switzerland, Singapore, and Israel.

Mechanism of Action

TEVIMBRA binds to PD-1 and blocks its interaction with PD-(L)1 and programmed death ligand 2 (PD-(L)2), releasing PD-1 pathway-mediated inhibition of the immune response, including the anti-tumor immune response. TEVIMBRA 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.[i] In pre-clinical studies, binding to Fcγ on macrophages has been shown to compromise the anti-tumor activity of anti-PD-1 antibodies through activation of antibody-dependent macrophage-mediated killing of T effector cells.[ii]

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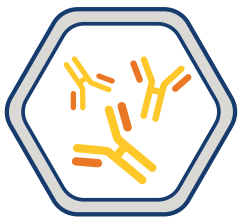
Pivotal Clinical Trials of TEVIMBRA as a Monotherapy

- **RATIONALE-301:** Phase 3 trial comparing TEVIMBRA with sorafenib as first-line (1L) treatment for patients with hepatocellular carcinoma (NCT03412773)[iii]
- **RATIONALE-302: Phase 3 trial comparing TEVIMBRA with chemotherapy as second-line (2L) treatment for patients with advanced ESCC (NCT03430843)**[iv]
- **RATIONALE-303:** Phase 3 trial comparing TEVIMBRA with docetaxel in the 2L/third-line (3L) setting in patients with NSCLC (NCT03358875)[v]
- **BGB-A317-314:** Phase 3 trial comparing TEVIMBRA with salvage chemotherapy in patients with relapsed or refractory (R/R) classical Hodgkin lymphoma (NCT04486391)[vii]
- **BGB-A317-203:** Phase 2 trial of TEVIMBRA in patients with R/R classical Hodgkin lymphoma (NCT03209973)[viii]
- **BGB-A317-204:** Phase 2 trial of TEVIMBRA in patients with locally advanced or metastatic urothelial bladder cancer (NCT04004221)[ix]
- **RATIONALE-208:** Phase 2 trial of TEVIMBRA in patients with previously treated unresectable hepatocellular carcinoma (NCT03419897)[x]
- **RATIONALE-209:** Phase 2 trial of TEVIMBRA in patients with microsatellite instability-high/mismatch repair deficient solid tumors (NCT03736889)[xi]

Pivotal Clinical Trials of TEVIMBRA as a Combination Therapy With Chemotherapy

- **RATIONALE-304:** Phase 3 trial of TEVIMBRA in combination with chemotherapy versus chemotherapy as 1L treatment for patients with advanced non-squamous NSCLC (NCT03663205)[xii]
- **RATIONALE-305:** Phase 3 trial of TEVIMBRA combined with chemotherapy versus placebo combined with chemotherapy as 1L treatment for patients with G/GEJ adenocarcinoma (NCT03777657)[xiii]
- **RATIONALE-306:** Phase 3 trial of TEVIMBRA in combination with chemotherapy versus placebo with chemotherapy as 1L treatment for patients with previously untreated advanced or metastatic ESCC (NCT03783442)[xiv]
- **RATIONALE-307:** Phase 3 trial of TEVIMBRA in combination with chemotherapy versus chemotherapy as 1L treatment for patients with advanced squamous NSCLC (NCT03594747)[xv]
- **RATIONALE-309:** Phase 3 trial of TEVIMBRA in combination with gemcitabine and cisplatin versus placebo combined with gemcitabine and cisplatin as 1L treatment for patients with recurrent or metastatic nasopharyngeal cancer (NCT03924986)[xvi]
- **RATIONALE-310:** Phase 3 trial comparing TEVIMBRA in combination with chemotherapy versus chemotherapy in patients with locally advanced or metastatic urothelial carcinoma (NCT03967977)[vi]
- **RATIONALE-311:** Phase 3 trial of TEVIMBRA versus placebo in combination with chemoradiotherapy in patients with localized ESCC (NCT03957590)[xvii]
- **RATIONALE-312:** Phase 3 trial of TEVIMBRA combined with platinum and etoposide versus placebo combined with platinum and etoposide in patients with extensive-stage small cell lung cancer (NCT04005716)[xviii]
- **RATIONALE-315:** Phase 3 trial of TEVIMBRA plus platinum-based doublet chemotherapy as neoadjuvant treatment followed by TEVIMBRA as adjuvant treatment versus placebo plus platinum-based doublet chemotherapy as neoadjuvant treatment followed by placebo as adjuvant treatment for patients with NSCLC (NCT04379635)[xix]

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



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.

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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 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.

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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.

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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 ≥ 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.

Please see full **Prescribing Information** including **Medication Guide**.

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