TEVIMBRA® (tislelizumab-jsgr)

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WHAT IS TEVIMBRA?

TEVIMBRA is a humanized immunoglobulin G4 (IgG4) anti-programmed cell death protein 1 (PD-1) monoclonal antibody with high affinity and binding specificity against PD-1.

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

Tislelizumab is the **first medicine to emerge from BeOne's immuno-oncology biologics program**, and the foundational asset of BeOne's solid tumor portfolio.

HOW TEVIMBRA WORKS

TEVIMBRA is designed to **bind to PD-1 and block 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 was **specifically engineered 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]

TEVIMBRA INDICATIONS IN THE UNITED STATES

TEVIMBRA is indicated for the treatment of adult patients with:

Esophageal cancer:
- In combination with platinum-containing chemotherapy for first-line treatment of unresectable or metastatic esophageal squamous cell carcinoma (ESCC) expressing PD-L1 (≥1), or
- As a single-agent for 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 first-line treatment of unresectable or metastatic HER2-negative gastric or gastroesophageal junction adenocarcinoma whose tumors express PD-L1 (≥1).

Gastric, gastroesophageal junction, or esophageal adenocarcinoma in combination with zanidatamab and fluoropyrimidine- and platinum-containing chemotherapy for first-line treatment of HER2-positive unresectable locally advanced or metastatic gastric, gastroesophageal junction, or esophageal adenocarcinoma.

Please see Important Safety Information on the following pages.

DISCOVERING TEVIMBRA

TEVIMBRA is **approved in more than 50 countries**, including the EU, China, Japan and the U.S., and **more than 2 million patients** have been treated globally with TEVIMBRA to date.

The global clinical development program includes:

Almost **15,000 patients enrolled to date**

In **30+ countries and regions**

Across **70 trials,** including 21 registration-enabling studies

Pivotal trials supporting the U.S. approvals of TEVIMBRA include:

- HERIZON-GEA-01 (NCT05152147): a Phase 3 trial, comparing zanidatamab plus chemotherapy, with and without tislelizumab, with trastuzumab plus chemotherapy in patients with **HER2+ advanced or metastatic GEA**[iii]
- RATIONALE-302 (NCT03430843): a Phase 3 trial of tislelizumab versus chemotherapy as second-line (2L) treatment for patients with advanced **ESCC.**[iv]
- RATIONALE-305 (NCT03777657): a Phase 3 trial of tislelizumab plus chemotherapy versus placebo plus chemotherapy as 1L treatment for patients with **G/GEJ.**[v]
- RATIONALE-306 (NCT03783442): a Phase 3 trial of tislelizumab plus chemotherapy versus placebo plus chemotherapy as 1L treatment for patients with **previously untreated advanced or metastatic ESCC**[vi]

IMPORTANT SAFETY INFORMATION[vii]

WARNINGS & PRECAUTIONS

- **Immune-Mediated Adverse Reactions (IMARs):** TEVIMBRA can cause immune-mediated adverse reactions, which may be severe or fatal and can occur in any organ system or tissue. Early identification and management of IMARs are essential to ensure safe use of PD-1/PD-L1 blocking antibodies. IMARs may occur at any time during or after treatment. Monitor for signs and symptoms of IMARs. Evaluate liver enzymes, creatinine, and thyroid function at baseline and periodically during treatment. For suspected IMARs, initiate appropriate workup to exclude alternative etiologies. Withhold or permanently discontinue TEVIMBRA based on severity and administer systemic corticosteroids or other immunosuppressants as clinically indicated. The IMARs listed were observed in clinical studies of TEVIMBRA (n=2390) and may not include all possible severe and fatal IMARs.
  - **Pneumonitis:** TEVIMBRA can cause immune-mediated pneumonitis, which can be fatal. Immune-mediated pneumonitis occurred in 4.7% of patients, including Grade 3-4 reactions in 1.7% and fatal events in 0.1%.
  - **Colitis:** TEVIMBRA can cause immune-mediated colitis, which can be fatal. Immune-mediated colitis occurred in 0.8% of patients, including Grade 3 reactions in 0.3%.

  - **Hepatitis:** TEVIMBRA can cause immune-mediated hepatitis, which can be fatal. Immune-mediated hepatitis occurred in 1.3% of patients, including Grade 3-4 reactions in 0.9%.
  - **Endocrinopathies:** TEVIMBRA can cause immune-mediated endocrinopathies, including adrenal insufficiency, hypophysitis/hypopituitarism, thyroid disorders, and type 1 diabetes mellitus. Reported rates included adrenal insufficiency (0.5%; Grade 3-4: 0.24%), hypophysitis/hypopituitarism (0.3%; all Grade 2), thyroiditis (1.0%; Grade 2: 0.5%), hyperthyroidism (4.9%; Grade 3: 0.04%), hypothyroidism (12.5%; Grade 3-4: 0.08%), and diabetes mellitus (0.7%; Grade 3-4: 0.4%).
  - **Nephritis with Renal Dysfunction:** TEVIMBRA can cause immune-mediated nephritis with renal dysfunction, which can be fatal. Immune-mediated nephritis with renal dysfunction occurred in 0.2% of patients, including Grade 3 reactions in 0.04%.
  - **Dermatologic Adverse Reactions:** TEVIMBRA can cause immune-mediated rash or dermatitis, including severe cutaneous adverse reactions. Immune-mediated dermatologic adverse reactions occurred in 13% of patients, including Grade 3-4 reactions in 1.2%; Stevens-Johnson syndrome occurred in 0.04% of patients.
  - **Other Immune-Mediated Adverse Reactions:** Other clinically significant immune-mediated adverse reactions occurred in <1% of patients and may involve cardiac/vascular, neurologic, ocular, gastrointestinal, musculoskeletal/connective tissue, endocrine, hematologic/immune systems (including solid organ transplant rejection), and myocarditis-myositis-myasthenia gravis (or myasthenia-like) overlap syndrome. Severe or fatal cases have been reported for some of these reactions.

- **Infusion-Related Reactions:** TEVIMBRA can cause infusion-related reactions, which may be severe or life-threatening. Infusion-related reactions occurred in 4.7% of patients (Grade ≥3: 0.2%). Monitor patients during infusion; slow the infusion for Grade 1 reactions, interrupt the infusion for Grade 2, and permanently discontinue TEVIMBRA for Grade 3 or higher.
- **Complications of Allogeneic Hematopoietic Stem Cell Transplantation (HSCT):** Fatal and serious complications, including graft-versus-host disease, have occurred in patients who receive allogeneic HSCT before or after treatment with PD-1/PD-L1 blockade. Complications may occur despite intervening therapy between treatment with PD-1/PD-L1 blockade and allogeneic HSCT. Monitor patients closely and intervene promptly.
- **Embryo-Fetal Toxicity:** TEVIMBRA can cause fetal harm and potential fetal death as shown in animal studies. Advise females of reproductive potential of the potential risk to a fetus. Verify pregnancy status prior to initiation of TEVIMBRA. Advise females of reproductive potential to use effective contraception during treatment and for 4 months after the last dose.

ADVERSE REACTIONS

The most common adverse reactions (≥20%), including lab abnormalities were:

- **Gastric, Gastroesophageal Junction, or Esophageal Adenocarcinoma (Combination with zanidatamab-hrii and chemotherapy, 1L):** diarrhea, nausea, anemia, decreased appetite,

vomiting, hypokalemia, fatigue, rash, decreased neutrophil count, decreased platelet count, peripheral neuropathy, infusion-related reaction, and increased AST.

- **Esophageal Cancer (Combination with chemotherapy, 1L):** 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.
- **Esophageal Cancer (Monotherapy, 1L):** 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.
- **Gastric Cancer (Combination with chemotherapy, 1L):** nausea, fatigue, decreased appetite, anemia, peripheral sensory neuropathy, vomiting, decreased platelet count, decreased neutrophil count, increased AST, diarrhea, abdominal pain, increased ALT, decreased white blood cell count, decreased weight, and pyrexia.

SPECIFIC POPULATIONS

Lactation: Advise women not to breastfeed during treatment and for 4 months after the last dose.

To report SUSPECTED ADVERSE REACTIONS, contact BeOne Medicines at 1-877-828-5596 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

INDICATIONS

TEVIMBRA is a programmed death receptor-1 (PD-1) blocking antibody indicated for the treatment of adults with:

Gastric, Gastroesophageal Junction, or Esophageal Adenocarcinoma

- In combination with zanidatamab-hrii and fluoropyrimidine- and platinum-containing chemotherapy for first-line treatment of HER2-positive (IHC 3+ or IHC 2+/ISH+) unresectable locally advanced or metastatic gastric, gastroesophageal junction, or esophageal adenocarcinoma.

Esophageal Cancer

- In combination with platinum-containing chemotherapy for first-line treatment of unresectable or metastatic esophageal squamous cell carcinoma (ESCC) expressing PD-L1 (≥1), **or**
- As a single-agent for unresectable or metastatic ESCC after prior systemic chemotherapy that did not include a PD-(L)1 inhibitor

Gastric Cancer

- In combination with fluoropyrimidine- and platinum-containing chemotherapy for first-line treatment of 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.

[i] BeOne. Data on File; 2024

[ii] Zhang T, Song X, Xu L, et al., The binding of an anti-PD-1 antibody to Fc R has a profound impact on its biological functions. Cancer Immunol Immunother. 2018;67(7):1079–1090

[iii] A Study of Zanidatamab in Combination With Chemotherapy Plus or Minus Tislelizumab in Patients With HER2-positive Advanced or Metastatic Gastric and Esophageal Cancers (HERIZON-GEA-01). ClinicalTrials.gov website. NCT05152147. Accessed July 29, 2026. https://clinicaltrials.gov/study/NCT05152147.

[iv] A Study of Tislelizumab (BGB-A317) in Combination With Chemotherapy as First Line Treatment in Participants With Advanced Esophageal Squamous Cell Carcinoma. ClinicalTrials.gov website. NCT03783442. Accessed August 25, 2026. https://clinicaltrials.gov/study/NCT03783442

[v] Tislelizumab in Combination With Chemotherapy as First-Line Treatment in Adults With Inoperable, Locally Advanced or Metastatic Gastric, or Gastroesophageal Junction Carcinoma. NCT03777657. Accessed August 25, 2026. https://clinicaltrials.gov/study/NCT03777657/.

[vi] A Study of Tislelizumab (BGB-A317) in Combination With Chemotherapy as First Line Treatment in Participants With Advanced Esophageal Squamous Cell Carcinoma. ClinicalTrials.gov website. NCT03783442. Last Accessed August 25, 2026. https://clinicaltrials.gov/study/NCT03783442.

[vii] TEVIMBRA® (tislelizumab-jsgr) Prescribing Information. San Carlos, CA: BeOne Medicines Ltd.; August 2026.