

Tislelizumab

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WHAT IS TISLELIZUMAB?

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

Tislelizumab is **approved in more than 50 countries**, including the EU, China, Japan and U.S.

More than 2 million patients have been treated globally to date with tislelizumab

HOW TISLELIZUMAB WORKS

- Tislelizumab is **designed to bind to PD-1, blocking its interaction with PD-(L)1 and PD-(L)2**, and enhancing the body's immune response against cancer cells.
- In addition, tislelizumab is **designed to minimize binding to Fc-gamma (Fcγ) receptors on macrophages, helping the body's immune cells to detect and fight tumors.**¹

TISLELIZUMAB AROUND THE WORLD



UNITED STATES

Tislelizumab is approved in the U.S. for the treatment of certain adult patients with esophageal squamous cell carcinoma (ESCC), gastric or gastroesophageal junction (G/GEJ) adenocarcinoma whose tumors express PD-L1 (≥ 1), and HER2+ gastroesophageal adenocarcinoma.



EUROPE

Tislelizumab is approved in the European Union (EU) for the treatment of certain adult patients with gastrointestinal, lung, and head and neck cancers. Tislelizumab is approved for a total of nine indications in solid tumors in the region.



GLOBAL

In China, tislelizumab is approved in 13 different solid tumor indications. Globally, more than 60 regulatory submissions for tislelizumab are under review by authorities in countries spanning five continents.

DISCOVERING THE FULL POTENTIAL OF TISLELIZUMAB

The global tislelizumab clinical development program spans multiple tumor types and disease settings:



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



In **30+ countries and regions**



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

PIVOTAL TRIALS SUPPORTING GLOBAL APPROVALS OF TISELIZUMAB

Tiselizumab as Monotherapy

- RATIONALE-301 ([NCT03412773](#)): a Phase 3 trial comparing tiselizumab with sorafenib as first-line (1L) treatment for patients with **hepatocellular carcinoma**.²
- RATIONALE-302 ([NCT03430843](#)): a Phase 3 trial comparing tiselizumab with chemotherapy as second-line (2L) treatment for patients with advanced **ESCC**.³
- RATIONALE-303 ([NCT03358875](#)): a Phase 3 trial comparing tiselizumab with docetaxel in the 2L/third-line (3L) setting in patients with **NSCLC**.⁴
- BGB-A317-314 ([NCT04486391](#)): a Phase 3 trial comparing tiselizumab with salvage chemotherapy in patients with **relapsed or refractory (R/R) classical Hodgkin Lymphoma**.⁵
- BGB-A317-203 ([NCT03209973](#)): a Phase 2 trial of tiselizumab in patients with **R/R classical Hodgkin Lymphoma**.⁶
- BGB-A317-204 ([NCT04004221](#)): a Phase 2 trial of tiselizumab in patients with **locally advanced or metastatic urothelial bladder cancer**.⁷
- RATIONALE-208 ([NCT03419897](#)): a Phase 2 trial of tiselizumab in patients with previously treated unresectable **hepatocellular carcinoma**.⁸
- RATIONALE-209 ([NCT03736889](#)): a Phase 2 trial of tiselizumab in patients with **microsatellite instability-high/mismatch repair deficient solid tumors**.⁹

Tiselizumab as a Combination Therapy with Chemotherapy

- HERIZON-GEA-01 ([NCT05152147](#)): a Phase 3 trial, comparing zanidatamab plus chemotherapy, with and without tiselizumab, to trastuzumab plus chemotherapy in patients with **advanced or metastatic HER2+ GEA**.¹⁰
- RATIONALE-304 ([NCT03663205](#)): a Phase 3 trial of tiselizumab in combination with chemotherapy versus chemotherapy as 1L treatment for patients with **advanced non-squamous NSCLC**.¹¹
- RATIONALE-305 ([NCT03777657](#)): a Phase 3 trial of tiselizumab combined with chemotherapy versus placebo combined with chemotherapy as 1L treatment for patients with **G/GEJ**.¹²
- RATIONALE-306 ([NCT03783442](#)): a Phase 3 trial of tiselizumab in combination with chemotherapy versus placebo with chemotherapy as 1L treatment for patients with **previously untreated advanced or metastatic ESCC**.¹³
- RATIONALE-307 ([NCT03594747](#)): a Phase 3 trial of tiselizumab in combination with chemotherapy versus chemotherapy as 1L treatment for patients with **advanced squamous NSCLC**.¹⁴
- RATIONALE-309 ([NCT03924986](#)): a Phase 3 trial of tiselizumab in combination with gemcitabine and cisplatin versus placebo combined with gemcitabine and cisplatin as 1L treatment for patients with **recurrent or metastatic nasopharyngeal cancer (NPC)**.¹⁵
- RATIONALE-310 ([NCT03967977](#)): a Phase 3 trial comparing tiselizumab in combination with chemotherapy versus chemotherapy in patients with **locally advanced or metastatic urothelial carcinoma**.¹⁶
- RATIONALE-311 ([NCT03957590](#)): a Phase 3 trial of tiselizumab versus placebo in combination with chemoradiotherapy in patients with localized **ESCC**.¹⁷
- RATIONALE-312 ([NCT04005716](#)): a Phase 3 trial of tiselizumab combined with platinum and etoposide versus placebo combined with platinum and etoposide in patients with **extensive-stage small cell lung cancer**.¹⁸
- RATIONALE-315 ([NCT04379635](#)): a Phase 3 trial of tiselizumab plus chemotherapy as neoadjuvant treatment followed by tiselizumab as adjuvant treatment versus placebo plus chemotherapy as neoadjuvant treatment followed by placebo as **adjuvant treatment for patients with NSCLC**.¹⁹

Select Important Safety Information

Serious and sometimes fatal adverse reactions occurred with TEVIMBRA treatment. Warnings and precautions include severe and fatal immune-mediated adverse reactions, including pneumonitis, colitis, hepatitis, endocrinopathies, nephritis with renal dysfunction, dermatologic adverse reactions, and solid organ transplant rejection. Other warnings and precautions include infusion-related reactions, complications of allogeneic HSCT, and embryo-fetal toxicity.

The most common adverse reactions ($\geq 20\%$), 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, 2L):** 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.

Disclaimer: Any information on the products or diseases contained herein is not intended to provide medical advice and/or treatment guidance. The information within is not intended for promotional purposes. Tislelizumab is not authorized in all countries; healthcare providers should consult the approved prescribing information in their respective countries.

REFERENCES

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