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 40 countries**, including the EU, China, Japan and U.S.

More than 1.3 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 to aid the body's immune cells to detect and fight tumors.**[1]

TISLELZUMAB AROUND THE WORLD

UNITED STATES

Tislelizumab is approved in the U.S. for the treatment of esophageal squamous cell carcinoma (ESCC) and gastric or gastroesophageal junction (G/GEJ) adenocarcinoma.

EUROPE

Tislelizumab is approved in the EU for the treatment of ESCC, G/GEJ and three non-small cell lung cancer (NSCLC) indications.

Tislelizumab is under regulatory review for extensive-stage small cell lung cancer (ES-SCLC) and nasopharyngeal cancer (NPC).

GLOBAL

In China, tislelizumab is approved across 12 different indications.

More than 20 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, and includes:

Almost **14,000 patients enrolled to date**

In **35 countries and regions**

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

PIVOTAL TRIALS SUPPORTING GLOBAL APPROVALS OF TISLELIZUMAB

Tislelizumab as Monotherapy

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

Tislelizumab as a Combination Therapy with Chemotherapy

- RATIONALE-304 (NCT03663205): a Phase 3 trial of tislelizumab in combination with chemotherapy versus chemotherapy as 1L treatment for patients with **advanced non-squamous NSCLC**[10]
- RATIONALE-305 (NCT03777657): a Phase 3 trial of tislelizumab combined with chemotherapy versus placebo combined with chemotherapy as 1L treatment for patients with **G/GEJ**[11]
- RATIONALE-306 (NCT03783442): a Phase 3 trial of tislelizumab in combination with chemotherapy versus placebo with chemotherapy as 1L treatment for patients with **previously untreated advanced or metastatic ESCC**[12]
- RATIONALE-307 (NCT03594747): a Phase 3 trial of tislelizumab in combination with chemotherapy versus chemotherapy as 1L treatment for patients with **advanced squamous NSCLC**[13]
- RATIONALE-309 (NCT03924986): a Phase 3 trial of tislelizumab 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)**[14]
- RATIONALE-310 (NCT03967977): a Phase 3 trial comparing tislelizumab in combination with chemotherapy versus chemotherapy in patients with **locally advanced or metastatic urothelial carcinoma**[15]
- RATIONALE-311 (NCT03957590): a Phase 3 trial of tislelizumab versus placebo in combination with chemoradiotherapy in patients with localized **ESCC**[16]
- RATIONALE-312 (NCT04005716): a Phase 3 trial of tislelizumab combined with platinum and etoposide versus placebo combined with platinum and etoposide in patients with **extensive-stage small cell lung cancer (ES-SCLC)**[17]
- RATIONALE-315 (NCT04379635): a Phase 3 trial of tislelizumab plus platinum-based doublet chemotherapy as neoadjuvant treatment followed by tislelizumab as adjuvant treatment versus placebo plus platinum-based doublet chemotherapy as neoadjuvant treatment followed by placebo as **adjuvant treatment for patients with NSCLC**[18]

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, dermatologic adverse reactions, nephritis with renal dysfunction, and solid organ transplant rejection. Other warnings and precautions include infusion-related reactions, complications of allogeneic HSCT, and embryo-fetal toxicity.

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.

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