ForPatients
*by Roche*

Gastroesophageal Junction AdenocarcinomaGastric CancerStomach Neoplasms

# A Study to Explore the Efficacy and Safety of Atezolizumab Plus Tiragolumab and Chemotherapy in 1st Line HER2 Negative Unresectable, Recurrent or Metastatic Gastric Cancer or Adenocarcinoma of Gastroesophageal Junction (GEJ)

| Trial Status | Trial Runs In | Trial Identifier |
|---|---|---|
| Terminated | 1 Country | NCT04933227 ML42913 |

*The information is taken directly from public registry websites such as ClinicalTrials.gov, EuClinicalTrials.eu, ISRCTN.com, etc., and has not been edited.*

## *Official Title:*

A Phase II, Single-Arm Study to Explore the Efficacy and Safety of Atezolizumab Plus Tiragolumab and Chemotherapy in 1st Line HER2 Negative Unresectable, Recurrent or Metastatic Gastric Cancer or Adenocarcinoma of Gastroesophageal Junction (GEJ)

## *Trial Summary:*

This study is designed to evaluate the efficacy and safety of atezolizumab plus tiragolumab in combination with capecitabine plus oxaliplatin (XELOX) for first-line treatment in participants with HER2-negative unresectable advanced, recurrent or metastatic gastric cancer (GC) or gastroesophageal junction adenocarcinoma (GEJ AC).

**Hoffmann-La Roche**
Sponsor

**Phase 2**
Phase

**NCT04933227 ML42913**
Trial Identifiers

## *Eligibility Criteria:*

| Gender | Age | Healthy Volunteers |
|---|---|---|
| All | #18 Years | No |

## *Inclusion Criteria:*

- Histologically confirmed (by enrolling center) gastric cancer or adenocarcinoma of GEJ (Siewert I-III)

- Unresectable locally advanced, unresectable recurrent, or metastatic disease that meets the following criteria: a) No prior systemic treatment for advanced disease, b) For patients receiving prior chemoradiotherapy or chemotherapy in the adjuvant or neoadjuvant setting, with an interval of at least 6 months between the final treatment and the diagnosis of advanced disease
- Measurable disease per Response Evaluation Criteria in Solid Tumors Version 1.1 (RECIST v1.1) as determined by investigator assessment
- Availability of a representative tumor specimen that is suitable for determination of PD-L1 and TIGIT expression
- Eastern Cooperative Oncology Group (ECOG) Performance Status of 0 or 1
- Life expectancy >/=3 months
- Adequate hematologic and end-organ function
- For women of childbearing potential: agreement to refrain from heterosexual intercourse or use contraception, and agreement to refrain from donating eggs
- For men: agreement to refrain from heterosexual intercourse or use contraceptive methods, and agreement to refrain from donating sperm.

## *Exclusion Criteria:*

- HER2-positive by local review, defined as either immunohistochemistry (IHC) score of 3+ or IHC 2+ with amplification proven by in situ hybridization (ISH) as assessed based on pretreatment tumor tissues
- Use of Chinese herbal medicine or Chinese patent medicines to control cancer within 7 days prior to initiation of study treatment
- Higher risk of bleeding or fistula caused by GEJ Siewert I invading adjacent organs
- Symptomatic, untreated, or actively progressing CNS metastases
- Uncontrolled tumor-related pain
- Uncontrolled pleural effusion, pericardial effusion, or ascites requiring recurrent drainage procedures (once monthly or more frequently)
- Uncontrolled or symptomatic hypercalcemia
- Active or history of autoimmune disease or immune deficiency
- History of idiopathic pulmonary fibrosis, organizing pneumonia, drug-induced pneumonitis, or idiopathic pneumonitis, or evidence of active pneumonitis on screening chest computed tomography scan
- Severe chronic or active infection within 4 weeks prior to initiation of study treatment
- Treatment with therapeutic oral or IV antibiotics within 2 weeks prior to initiation of study treatment
- Major surgical procedure, other than for diagnosis, within 4 weeks prior to initiation of study treatment, or anticipation of need for a major surgical procedure during the study
- History of malignancy within 5 years prior to screening, with the exception of the cancer under investigation in this study and malignancies with a negligible risk of metastasis or death
- Any other disease, medical condition, metabolic dysfunction, alcohol or drug abuse or dependence, physical examination finding, clinical laboratory finding that contraindicates the use of an investigational drug, may affect the interpretation of the results, or may render the patient at high risk from treatment complications
- Prior treatment with CD137 agonists, T-cell co-stimulating, or immune checkpoint blockade therapies, including anti-CTLA-4, anti-PD-1, anti-PD-L1, and anti-TIGIT therapeutic antibodies
- Treatment with systemic immunostimulatory agents or any investigational therapy within 4 weeks or 5 drug-elimination half-lives (whichever is longer) prior to initiation of study treatment
- Treatment with systemic immunosuppressive medication within 2 weeks prior to initiation of study treatment
- Treatment with a live, attenuated vaccine within 4 weeks prior to initiation of study treatment
- Known allergy or hypersensitivity to any component of atezolizumab, tiragolumab, capecitabine or oxaliplatin formulations
- Pregnant or breastfeeding.

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