ForPatients
*by Roche*

Gastroesophageal Junction AdenocarcinomaGastric Cancer

# A Study of Atezolizumab and Trastuzumab in Combination With Capecitabine and Oxaliplatin in Patients With HER2 Positive Locally Advanced Resectable Gastric Cancer of Adenocarcinoma of Gastroesophageal Junction

| Trial Status | Trial Runs In | Trial Identifier |
|---|---|---|
| Active, not recruiting | 1 Country | NCT04661150 ML42058 |

*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, Randomized Study of Atezolizumab (Anti-PD-L1 Antibody) and Trastuzumab in Combination With Capecitabine and Oxaliplatin (Xelox) in Patients With HER2 Positive Locally Advanced Resectable Gastric Cancer of Adenocarcinoma of Gastroesophageal Junction (GEJ)

## *Trial Summary:*

This is a phase II, multicenter, randomized, open-label study designed to evaluate the efficacy and safety of perioperative trastuzumab+XELOX with / without atezolizumab in participants eligible for surgery with locally advanced HER2-positive gastric cancer or adenocarcinoma of GEJ.

**Hoffmann-La Roche**
Sponsor

**Phase 2**
Phase

**NCT04661150 ML42058**
Trial Identifiers

## *Eligibility Criteria:*

| Gender | Age | Healthy Volunteers |
|---|---|---|
| All | #18 Years & # 75 Years | No |

## *Inclusion Criteria:*

- Histologically confirmed gastric cancer or adenocarcinoma of GEJ

- HER2-positive status defined as either IHC score of 3+ or IHC 2+ with amplification proven by in situ hybridization (ISH) as assessed by local review based on pretreatment endoscopic biopsies.
- Clinical stage at presentation: cT3/T4a/T4b, or N+, M0 as determined by AJCC staging system, 8th edition
- Availability of pretreatment tumor specimen for biomarker analysis by central lab
- Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1
- Life expectancy >= 12 weeks
- Adequate hematologic and end-organ function
- For female patients of childbearing potential, agreement (by patient) to remain abstinent (refrain from heterosexual intercourse) or to use highly effective form(s) of contraception during the treatment period and to continue its use for at least i) 5 months after the last dose of atezolizumab, ii) 7 months after the last dose of trastuzumab, or iii) 6 months after the last dose of capecitabine or oxaliplatin, whichever is longer.
- For men: agreement to remain abstinent (refrain from heterosexual intercourse) or use a condom, and agreement to refrain from donating sperm

## *Exclusion Criteria:*

- Stage IV (metastatic) or unresectable gastric/GEJ cancer determined by investigators
- Prior systemic therapy for treatment of gastric cancer
- History of malignancy other than GC within 5 years prior to screening, with the exception of malignancies with a negligible risk of metastasis or death
- Cardiopulmonary dysfunction
- Dyspnea at rest
- Active or history of autoimmune disease or immune deficiency with the following exceptions: (a) Patients with a history of autoimmune-mediated hypothyroidism who are on thyroid-replacement hormone are eligible for the study. (b) Patients with controlled Type 1 diabetes mellitus who are on an insulin regimen are eligible for the study. (c) Patients with eczema, psoriasis, lichen simplex chronicus, or vitiligo with dermatologic manifestations only are eligible for the study provided allof following conditions are met: (i) Rash must cover < 10% of body surface area (ii) Disease is well controlled at baseline and requires only low-potency topical corticosteroids (iii) No occurrence of acute exacerbations of the underlying condition requiring psoralen plus ultraviolet A radiation, methotrexate, retinoids, biologic agents, oral calcineurin inhibitors, or high-potency or oral corticosteroids within the previous 12 months
- History of idiopathic pulmonary fibrosis, organizing pneumonia, drug-induced pneumonitis, idiopathic pneumonitis, or evidence of active pneumonitis on screening chest CT scan
- Active tuberculosis
- Patients with active hepatitis B
- Patients with active hepatitis C