ForPatients
by Roche

Gastric and Gastroesophageal Junction Carcinoma

An Umbrella Study Evaluating the Efficacy and Safety of Multiple Treatment Combinations in Patients With Gastric or Gastroesophageal Junction Carcinoma

Trial Status	Trial Runs In	Trial Identifier
Active, not recruiting	1 Country	NCT05251948 YO43408

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 Ib/II, Open-Label, Multicenter, Randomized Umbrella Study Evaluating the Efficacy and Safety of Multiple Treatment Combinations in Patients With Gastric or Gastroesophageal Junction Carcinoma (MORPHEUS C-Gastric and Gastroesophageal Junction Carcinoma)

Trial Summary:

This is a Phase Ib/II, open-label, multicenter, randomized umbrella study in participants with advanced gastric carcinoma (GC) or gastroesophageal junction carcinoma (GEJC). The study is designed with the flexibility to open new treatment arms as new treatments become available, close existing treatment arms that demonstrate minimal clinical activity or unacceptable toxicity, and modify the participant population. Cohort 1 will enroll participants with inoperable locally advanced, metastatic, or advanced GC or GEJC, with adenocarcinoma confirmed as the predominant histology, who have not received prior systemic therapy for advanced or metastatic disease. Eligible participants will initially be randomly assigned to one of treatment arms (Stage 1). Participants who experience loss of clinical benefit or unacceptable toxicity during Stage 1 may be eligible to receive treatment with a different treatment combination (Stage 2). When a Stage 2 treatment combination is available, this will be introduced by amending the protocol.

Hoffmann-La Roche	Phase 1/Phase 2
Sponsor	Phase

NCT05251948 YO43408
Trial Identifiers

Eligibility Criteria:

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Gender	Age	Healthy Volunteers
All	**#18 Years**	**No**

Inclusion Criteria:

Inclusion Criteria for Stage 1:

- ECOG Performance Status of 0 or 1
- Inoperable locally advanced, metastatic, or advanced GC or GEJC, with adenocarcinoma confirmed as the predominant histology
- No prior systemic treatment for advanced or metastatic disease
- Life expectancy >= 3 months, as determined by the investigator
- Human epidermal growth factor receptor 2 (HER2)-negative tumors
- Measurable disease according to RECIST v1.1
- Adequate hematologic and end-organ function
- Patients without hepatitis B virus (HBV) infection at screening
- Negative hepatitis C virus (HCV) antibody test at screening, or positive HCV antibody test followed by a negative HCV RNA test at screening
- Negative HIV test at screening
- For women of childbearing potential: agreement to remain abstinent or use contraception, and agreement to refrain from donating eggs, as outlined for each specific treatment arm
- For men: agreement to remain abstinent or use contraception, and agreement to refrain from donating sperm, as outlined for each specific treatment arm

Exclusion Criteria:

Exclusion Criteria for Stage 1:

- Prior treatment with CD137 agonists or immune checkpoint blockade therapies
- Treatment with investigational therapy within 28 days prior to initiation of study treatment
- Any contraindications to any of the study drugs of the chemotherapy regimen
- Eligible only for the control arm
- Patients with a signet ring cells dominant carcinoma
- Symptomatic, untreated, or actively progressing CNS metastases
- History of leptomeningeal disease
- Active or history of autoimmune disease or immune deficiency
- Significant cardiovascular disease within 3 months prior to initiation of study treatment, unstable arrhythmia, or unstable angina
- History of malignancy other than GC or GEJC within 2 years prior to initiation of study treatment, with the exception of malignancies with a negligible risk of metastasis or death

Exclusion Criteria for Tiragolumab-Containing Arm:

- Prior treatment with an anti-TIGIT agent
- Active Epstein-Barr virus (EBV) infection or known or suspected chronic active EBV infection at screening