Zolbetuximab is a chimeric IgG1 monoclonal antibody that specifically binds to CLDN18.2 and mediates cell death through antibody-dependent cell-mediated cytotoxicity and tumor cell death.

In preclinical models of GC/GEJ treatment with chemotherapeutic serum tumor cell lines to zolbetuximab-mediated mechanisms by increasing CLDN18.2 expression; improved antitumor activity was observed in xenograft mice treated with zolbetuximab plus chemotherapy compared with mice treated with chemotherapy alone.

Zolbetuximab, as a single agent and in combination with chemotherapy, was cytotoxicly well tolerated and demonstrated antitumor activity in patients with CLDN18.2-positive (CLDN18.2+/HER2−) patients with advanced refractory locally-advanced or metastatic GC/GEJ who had received at least 1 prior line of chemotherapy, single-agent zolbetuximab demonstrated a clinical benefit rate of 21%.

**Methods**

**Study Design and Objectives**

This is a double-blind, placebo-controlled, phase 3, international trial (NCT03504397) to evaluate the efficacy and safety of zolbetuximab plus mFOLFOX6 compared with placebo plus mFOLFOX6 in the first-line treatment of patients with CLDN18.2+/HER2− (CLDN18.2+/HER2−) locally advanced refractory locally-advanced or metastatic GC/GEJ.

**Comparison of overall survival (OS) is the secondary key efficacy objective; other secondary objectives included the evaluation of objective response rate (ORR) and duration of response (DOR)**.

**Trial Design**

**General Information**

- **Consent and Screening Period**
- **Treatment Discontinuation**
- **Treatment Discontinuation**

**Study Assessments**

**Statistical Analysis**

**Sponsorship and Acknowledgments**

**Conflict of Interest**

**References**


