NOW ENROLLING

The BRIGHTER Trial

A Phase III Randomized, Double-Blind, Placebo-Controlled Clinical Trial of BBI608 plus Weekly Paclitaxel vs. Placebo plus Weekly Paclitaxel in Adult Patients with Advanced, Previously Treated Gastric and Gastro-Esophageal Junction Adenocarcinoma

Eligible Patient Population

- Unresectable metastatic Gastric or GEJ adenocarcinoma
- One prior line of platinum/ fluoropyrimidine-based therapy in advanced setting
- (Neo)adjuvant taxane allowed if progression occurred ≥6 months following completion of therapy
- PS 0 or 1

1:1 RANDOMIZE

- **BBI608* + Paclitaxel****
- **Placebo + Paclitaxel****

*BBI608/Placebo 480 mg PO BID.
**Paclitaxel 80 mg/m² IV 3 out of 4 weeks.

Primary Endpoint

Overall survival

Secondary Endpoints

- Progression-free survival
- Objective response rate
- Disease control rate
- Safety

Key Inclusion Criteria

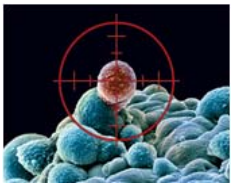
- Cytologically or histopathologically confirmed advanced gastric or GEJ adenocarcinoma that is metastatic or locally advanced and unresectable
- Failed treatment with one regimen containing at least a platinum/fluoropyrimidine doublet for unresectable or metastatic disease. Treatment failure is defined as progression of disease (clinical or radiologic) during first-line treatment for unresectable or metastatic disease, or ≤6 months after last dose of first-line treatment
- Paclitaxel therapy is appropriate for the patient and is recommended by the Investigator

Study locations

Global sites currently include Belgium, France, Germany, Hungary, Israel, Italy, Lithuania, Poland, Romania, Brazil, Spain, Belgium, Estonia Russian Federation, Bulgaria, Czech Republic, United Kingdom, Australia, Japan, Korea, Canada, and the United States.

About BBI608

BBI608 is an orally administered investigational agent not approved by the U.S. FDA, designed to inhibit cancer stem cell pathways by targeting STAT3.



BBI608 is a first-in-class, orally administrated, cancer stemness inhibitor.

Cancer Stem Cells (CSC) are a new promising target for novel anticancer agent development