Study of TAS-102 or Placebo Plus BSC in Patients With Metastatic Gastric Cancer

This study is currently recruiting participants. (see Contacts and Locations)

Verified June 2016 by Taiho Oncology, Inc.

Sponsor:
Taiho Oncology, Inc.

Information provided by (Responsible Party):
Taiho Oncology, Inc.

ClinicalTrials.gov Identifier:
NCT02500043

First received: July 13, 2015
Last updated: June 24, 2016
Last verified: June 2016
History of Changes

Purpose

The purpose of this trial is to compare the effects of **TAS-102** and best supportive care (BSC) with Placebo (an inactive drug) and best supportive care on metastatic gastric cancer.

Condition	Intervention	Phase
Refractory Metastatic Gastric Cancer	Drug: **TAS-102** Drug: Placebo	Phase 3

Study Type: Interventional
Study Design: Allocation: Randomized
Endpoint Classification: Safety/Efficacy Study
Intervention Model: Parallel Assignment
Masking: Double Blind (Subject, Caregiver, Investigator, Outcomes Assessor)
Primary Purpose: Treatment

Official Title: Randomized, Double-blind, Phase 3 Study Evaluating **TAS-102** Plus Best Supportive Care (BSC) Versus Placebo Plus BSC in Patients With Metastatic Gastric Cancer Refractory to Standard Treatments

Resource links provided by NLM:

MedlinePlus related topics: Cancer Stomach Cancer

Genetic and Rare Diseases Information Center resources: Stomach Cancer

U.S. FDA Resources

Further study details as provided by Taiho Oncology, Inc.:

Primary Outcome Measures:

- Overall Survival [Time Frame: Up to 3 years] [Designated as safety issue: No]

  OS is defined as the time from the date of randomization to the date of death.

Secondary Outcome Measures:

- Progression-Free Survival (PFS) [Time Frame: Up to 3 years] [Designated as safety issue: No]

  PFS is defined as the time from the date of randomization until radiological disease progression or death due to any cause.

- Safety and Tolerability [Time Frame: Up to 3 years] [Designated as safety issue: No]

  Safety and Tolerability is defined as AEs graded using NCI criteria for AEs (CTCAE).

Other Outcome Measures:

- Overall Response Rate (ORR) [Time Frame: Up to 3 years] [Designated as safety issue: No]

  ORR is defined as the proportion of patients with objective evidence of complete response or partial response.

- Disease Control Rate (DCR) [Time Frame: Up to 3 years] [Designated as safety issue: No]

  DCR is defined as the proportion of patients with objective evidence of complete response, partial response or SD.

- Time to Deterioration of Eastern Cooperative Oncology Group (ECOG) Performance Status to Score of 2 or Higher [Time Frame: Up to 3 years] [Designated as safety issue: No]

  The time to deterioration of ECOG performance status is defined as the time from randomization to the first date on which an ECOG performance status score of 2 or higher is observed.

- Quality of Life [Time Frame: Up to 3 years] [Designated as safety issue: No]

  Quality of life is defined as an assessment for health-related quality of life of cancer patients.

Estimated Enrollment:	500
Study Start Date:	December 2015
Estimated Study Completion Date:	December 2018
Estimated Primary Completion Date:	June 2018 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: **TAS-102** 35 mg/m2/dose of **TAS-102** orally, twice daily on days 1-5 and days 8-12 of each 28-day cycle. Number of cycles: approximately 4 or until discontinuation criteria is met.	Drug: **TAS-102** 35 mg/m2/dose of **TAS-102** orally, twice daily on days 1-5 and days 8-12 of each 28-day cycle.
Experimental: Placebo 35 mg/m2/dose of placebo orally, twice daily on days 1-5 and days 8-12 of each 28-day cycle. Number of cycles: approximately 4 or until discontinuation criteria is met.	Drug: Placebo 35 mg/m2/dose of placebo orally, twice daily on days 1-5 and days 8-12 of each 28-day cycle.

Detailed Description:
This is a multinational, double-blind, two-arm, parallel, randomized, Phase 3 study evaluating the efficacy and safety of TAS-102 plus BSC versus placebo plus BSC in patients with metastatic gastric cancer who have previously received at least 2 prior regimens for advanced disease. Eligible patients will be centrally randomized (2:1) to TAS-102 + BSC (experimental arm) or placebo + BSC (control arm).

Eligibility

Ages Eligible for Study:	18 Years and older (Adult, Senior)
Genders Eligible for Study:	Both
Accepts Healthy Volunteers:	No

Criteria

Inclusion Criteria:

1. Has histologically confirmed non-resectable, metastatic gastric adenocarcinoma including adenocarcinoma of the gastroesophageal junction.
2. Has previously received at least 2 prior regimens for advanced disease and were refractory to or unable to tolerate their last prior therapy.
3. Has measureable or nonmeasurable disease as defined by RECIST 1.1 criteria.
4. Is able to take medications orally (ie, no feeding tube).
5. Has an ECOG performance status of 0 or 1.
6. Has adequate organ function as defined by protocol defined labs.
7. Women of childbearing potential must have a negative pregnancy test and must agree to adequate birth control if conception is possible. Males must agree to adequate birth control.

Exclusion Criteria:

1. Has certain serious illnesses or medical conditions
2. Has had certain other recent treatment e.g. major surgery, anticancer therapy, extended field radiation, received investigational agent within the specified time frames prior to study drug administration.
3. Has previously received TAS-102.
4. Has unresolved toxicity of greater than or equal to CTCAE Grade 2 attributed to any prior therapies.
5. Is a pregnant or lactating female.

Contacts and Locations

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the Contacts provided below. For general information, see Learn About Clinical Studies.

Please refer to this study by its ClinicalTrials.gov identifier: NCT02500043

Contacts

Contact: Robert Winkler, MD 609-750-5300 rwinkler@taihooncology.com

Show 47 Study Locations

Sponsors and Collaborators

Taiho Oncology, Inc.

More Information

Responsible Party:	Taiho Oncology, Inc.
ClinicalTrials.gov Identifier:	NCT02500043 History of Changes
Other Study ID Numbers:	TO-**TAS-102-**302 2015-002683-16
Study First Received:	July 13, 2015
Last Updated:	June 24, 2016
Health Authority:	United States: Food and Drug Administration Japan: Pharmaceuticals and Medical Devices Agency

Keywords provided by Taiho Oncology, Inc.:
Gastric Cancer
Metastatic Gastric Cancer

Additional relevant MeSH terms:

Stomach Neoplasms	Neoplasms
Gastrointestinal Neoplasms	Digestive System Diseases
Digestive System Neoplasms	Gastrointestinal Diseases
Neoplasms by Site	Stomach Diseases

ClinicalTrials.gov processed this record on July 04, 2016