Working to provide answers for gastric cancer

Gastric cancer, including cancers of the gastroesophageal junction and esophagus, is the fifth most frequently diagnosed cancer worldwide.[1] Many cases of gastric cancer go undetected until they are advanced or metastatic, when treatment options can be limited.[1] That's why exploring potential treatment options through clinical research is so important.

The investigational treatment, pumitamig, is a bispecific antibody designed to target both PD-L1 and VEGF-A, aiming to relieve immunosuppression and inhibit tumor angiogenesis in the tumor microenvironment.[2]

[1] https://www.ncbi.nlm.nih.gov/books/NBK459142/

[2] https://pmc.ncbi.nlm.nih.gov/articles/PMC8678608/

Starting the conversation

This clinical trial has the potential to offer a step forward in advancing research for people with gastric, gastroesophageal junction, or esophageal cancer, who have not yet received treatment for advanced or metastatic disease. The **ROSETTA Gastric-204 Trial** is currently open and actively enrolling participants.

Physicians are encouraged to review their patients' charts to identify potential candidates for participation.

Consider referring patients who:

- Are ≥ 18 years old
- Were previously untreated with systemic treatment for advanced/ metastatic disease, histologically or cytologically confirmed advanced or metastatic GC, GEJC or distal EAC; GEJ involvement can be confirmed via biopsy, endoscopy, or imaging*
- Have documented HER2 negative cancer
- Have documented PD-L1PD-L1 > 1

** Patients may have received chemotherapy if it was completed at least 6 months before the diagnosis of advanced or metastatic disease.*

Additional eligibility criteria will be assessed by the trial team.

For more information:

This trial is being conducted by:

Bristol Myers Squibb®

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A clinical trial for gastric cancer

ROSETTA GASTRIC-204

The ROSETTA Gastric-204 Trial (CA266-0004)

A guide for referring physicians

A Blinded, Randomized, Phase 2/3 Trial to Evaluate the Efficacy and Safety of Pumitamig (BMS-986545) in Adult Participants with Previously Untreated Advanced or Metastatic Gastric, Gastroesophageal Junction, or Esophageal Adenocarcinoma

Bristol Myers Squibb®

Objectives of the ROSETTA Gastric-204 Trial

The main objectives of the **ROSETTA Gastric-204 Trial** include:

To evaluate the efficacy of pumitamig in combination with chemotherapy in adult participants with previously untreated advanced or metastatic gastric, gastroesophageal junction, or esophageal cancer

To evaluate the safety of pumitamig in combination with chemotherapy in this population

To compare pumitamig plus chemotherapy with nivolumab plus chemotherapy, with a focus on overall response in Phase 2 and progression-free survival in Phase 3, along with additional outcomes such as overall survival, duration of response, and disease control rate

Trial design at a glance

Trial participation is divided into the following periods:

Screening period (up to 35 days)

Potential participants will meet with the trial team to determine eligibility, including assessments of tumor genetics, performance status, and measurable disease.

Trial treatment period*

Participants will be randomized to receive either:

- Investigational treatment (pumitamig) + chemotherapy
- Comparator (nivolumab) + chemotherapy

*The trial treatment duration depends on the participant's response to therapy and tolerability.

Follow-up period

After completing the treatment period, all trial participants will be monitored for safety (for at least 90 days), and for survival status at regular intervals, up to 3 years post-treatment. During this period, trial participants will no longer take the investigational treatment.

Discussing the trial opportunity with your patients

When discussing this clinical trial with your patients, here are some key points to mention:

The **ROSETTA Gastric-204 Trial** is evaluating an investigational treatment for previously untreated advanced or metastatic gastric, gastroesophageal junction, or esophageal cancer.

The investigational treatment is administered intravenously (IV infusion) in combination with investigator's choice of chemotherapy, or standard-of-care with investigator's choice of chemotherapy.

Trial participation will last until disease progression, unacceptable toxicity, withdrawal, or trial end, with treatment visits every 2 or 3 weeks during the treatment period (frequency depends on chemotherapy regimen).

Qualified participants will receive all trial-related care and trial-related treatment at no cost, with possible reimbursement for travel and expenses.

This trial may be an appealing choice for adults who have not received prior systemic therapy for advanced or metastatic gastric, gastroesophageal junction, or esophageal cancer, especially those who are seeking alternatives to standard options.

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