

GAT014 (Inclusion Criteria)

Inclusion Criteria

Subjects must meet all of the following criteria to be eligible for randomization into the study:

1. Sign and date the Tissue Screening and Main ICFs, prior to the start of any study-specific qualification procedures.

2. Adults (according to local regulation) and able to provide informed consent for study participation.

3. Pathologically documented gastric and GEJ adenocarcinoma that has been previously treated in the metastatic setting (unresectable, locally advanced, or metastatic disease).

4. Progression on or after first-line therapy with a trastuzumab or approved trastuzumab biosimilar-containing regimen.

Note: Prior adjuvant therapy with a trastuzumab-containing regimen can be counted as a line of therapy if the subject progressed on or within 6 months of completing adjuvant therapy.

5. Is willing and able to provide an adequate tumor sample for tissue screening to confirm HER2 status by Central Laboratory.

6. Centrally confirmed HER2-positive (IHC 3+ or IHC 2+ and evidence of HER2 amplification by ISH) as classified by ASCO-CAP on a tumor biopsy obtained after progression on or after a first-line trastuzumab or approved trastuzumab biosimilar-containing regimen.

7. ECOG PS of 0 or 1 at both Screening and within 3 days prior to randomization.

8. Adequate laboratory parameters as evidenced by the blood counts within 14 days of randomization.

9. Has adequate treatment washout period before randomization/enrollment.

10. LVEF \geq 50% within 28 days before randomization per echocardiogram (ECHO) or multigated acquisition (MUGA) scan.

11. Recovered from the effects of any prior surgery or radiotherapy.

12. Men and women of reproductive/childbearing potential must agree to use a highly effective form of contraception or avoid intercourse during and upon completion of the study and for at least 7 months for female subjects and 4 months for male subjects after the last dose of study drug. Methods considered as highly effective methods of contraception are detailed in Section 10.3.4. For Ram + PTX, sites should follow local label or institutional guidelines.

13. Male subjects must not freeze or donate sperm starting at Screening and throughout the study period, and at least 4 months after the final study drug administration. Preservation of sperm should be considered prior to randomization/enrollment in this study. For Ram + PTX, sites should follow local label or institutional guidelines.

14. Female subjects must not donate, or retrieve for their own use, ova from the time of Screening and throughout the study Treatment Period, and for at least 7 months after the final study drug administration. For Ram + PTX, sites should follow local label or institutional guidelines.

15. Is willing and able to comply with scheduled visits, drug administration plan, laboratory tests, other study procedures, and study restrictions.