GAT015 Inclusion Criteria

Key Inclusion Criteria:

1. Age ≥ 18 years old (or legal adult age within country, whichever is older)
2. Histologically documented gastric or gastroesophageal junction adenocarcinoma (not amenable to curative therapy)

   Primary tumor locations will be classified following the American Joint Committee on Cancer/Union for International Cancer Control (AJCC/UICC) 8th edition
3. Disease that is unresectable, locally advanced or metastatic (not amenable to curative therapy)
4. Eastern Cooperative Oncology Group (ECOG) performance status of 0 to 1
5. Adequate organ function
6. Measurable disease or non-measurable, but evaluable disease, according to RECIST v1.1
7. Subject has no contraindications to mFOLFOX6 chemotherapy or nivolumab
8. No prior treatment for metastatic or unresectable disease except for a maximum of 1 dose of mFOLFOX6 with or without nivolumab;
   - Prior adjuvant, neo-adjuvant, and peri-operative therapy is allowed, provided it has been completed more than 6 months prior to the first dose of study treatment
9. FGFR2b ≥10% 2+/3+ Tumor Cell as determined by centrally performed IHC testing, based on tumor sample either archival (obtained within 6 months/180 days prior to signing pre-screening informed consent, 12 slides recommended) or a fresh biopsy.
10. Untreated or symptomatic CNS metastases and leptomeningeal disease
11. Impaired cardiac function or clinically significant cardiac disease
12. Peripheral sensory neuropathy grade 2 or higher
13. Active infection requiring systemic treatment or any uncontrolled infection within 14 days prior to first dose of study treatment
14. Known human immunodeficiency virus (HIV) infection with CD4+ T-cell (CD4+) counts < 350 cells/µL, hepatitis C infection (subjects with hepatitis C that achieve a sustained virologic response following antiviral therapy are allowed), or hepatitis B infection (subjects with hepatitis B surface antigen or core antibody that achieve sustained virologic response with antiviral therapy directed at hepatitis B are allowed)

15. Any anticancer therapy or immunotherapy within 4 weeks prior to first dose of study treatment (except for a maximum of 1 dose of mFOLFOX6 with or without nivolumab)

    * Palliative radiotherapy is allowed, provided it has been completed more than 14 days prior to the first dose of study treatment

    * All treatment-related toxicity needs to be resolved to grade ≤ 1 prior to the first dose of study treatment, with the exception of alopecia or toxicities considered irreversible (defined as having been present and stable for more than 21 days) which are not otherwise described in the exclusion criteria