

GAT015 Exclusion Criteria

Key Exclusion Criteria:

1. History of interstitial lung disease
2. Known positive HER2 status (as defined by a positive IHC test of 3+ or IHC2+ with positive in situ hybridization [ISH])
3. History or evidence of systemic disease or ophthalmological disorders requiring chronic use of ophthalmic corticosteroids
4. Evidence of any ongoing ophthalmologic abnormalities or symptoms that are acute (within 4 weeks) or actively progressing
5. Unwillingness to avoid use of contact lenses during study treatment
6. History of solid organ transplantation
7. Active autoimmune disease that has required systemic treatment (except replacement therapy) within the past 2 years or any other diseases requiring immunosuppressive therapy while on study
8. Immunosuppressive doses of systemic medications of > 10 mg/day of prednisone or equivalent must be discontinued at least 2 weeks before the first dose of study drug. Short courses of high dose corticosteroids and/or continuous low dose of prednisone (< 10 mg/day) are allowed. In addition, inhaled, intranasal, intraocular, and/or joint injections of corticosteroids are allowed
9. Subjects who experienced severe, life-threatening or recurrent (Grade 2 or higher) immune mediated adverse events or infusion-related reactions including those that lead to permanent discontinuation while on treatment with immune-oncology agents
10. History of other malignancy within the past 2 years, except:
 - Curatively treated non-melanoma skin malignancy
 - Cervical cancer in situ
 - Curatively treated uterine cancer stage I
 - Curatively treated ductal or lobular breast carcinoma in situ and not currently receiving any systemic therapy
 - Localized prostate cancer that has been treated surgically with curative intent and presumed cured

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11. Evidence of, or recent (within 6 months) history of, corneal defects, corneal ulcerations, keratitis, or keratoconus, history of corneal transplant, or other known abnormalities of the cornea that may pose an increased risk of developing a corneal ulcer. Recent (within 6 months) corneal surgery or ophthalmic laser treatment
12. Major surgical procedures within 28 days prior to first dose of study treatment.
13. Prior treatment with any selective inhibitor of the FGF-FGFR pathway
14. Currently receiving treatment in another investigational device or drug study within 28 days of first dose of study treatment or during this clinical study. Other investigational procedures while participating in this study are excluded

Other Exclusion Criteria:

1. Female subjects of childbearing potential unwilling to use protocol specified method of contraception (see Section 11.5) during treatment and for an additional 9 months after the last dose of protocol-mandated therapy
2. Female subjects who are breastfeeding or plan to breastfeed while on study through 5 months after the last dose of protocol-mandated therapy
3. Female subjects planning to become pregnant while on study through 9 months after the last dose of protocol-mandated therapy

(Female subjects of childbearing potential with a positive pregnancy test assessed at screening and within 72 hours prior to first dose of study treatment by a highly sensitive urine or serum pregnancy test)
4. Male subjects with a female partner of childbearing potential who are unwilling to practice sexual abstinence (refrain from heterosexual intercourse) or use contraception during treatment and for an additional 6 months after the last dose of protocol-mandated therapy. Refer to Section 11.5 (of protocol) for additional contraceptive information
5. Male subjects unwilling to abstain from donating sperm during treatment and for an additional 6 months after the last dose of protocol-mandated therapy
6. Unlikely to be available to complete all protocol-required study visits or procedures, and/or to comply with all required study procedures within the subject's capacity to the best of the subject and investigator's knowledge
7. History or evidence of any other clinically significant disorder, condition or disease that, in the opinion of the investigator or Amgen physician, if consulted, would pose a risk to subject safety or interfere with the study evaluation, procedures or completion

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8. Known allergy, hypersensitivity or contraindication to components of the bemarituzumab formulation including polysorbate