

Solid TumorsCancer

A Phase I Study of BTRC4017A in Participants With Locally Advanced or Metastatic HER2-Expressing Cancers

Trial Status Active, not recruiting	Trial Runs In 13 Countries	Trial Identifier NCT03448042 GO40311
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The information is taken directly from public registry websites such as ClinicalTrials.gov, EuClinicalTrials.eu, ISRCTN.com, etc., and has not been edited.

Official Title:

A Phase Ia/Ib, Open-Label, Dose-Escalation Study of the Safety and Pharmacokinetics of Runimotamab Administered Intravenously as a Single Agent and in Combination With Trastuzumab in Patients With Locally Advanced or Metastatic HER2-Expressing Cancers

Trial Summary:

This study will evaluate the safety, tolerability, and pharmacokinetics of Runimotamab administered intravenously as a single agent and in combination with Trastuzumab in participants with locally advanced or metastatic Human Epidermal Growth Factor Receptor 2 (HER2)-expressing cancers.

Genentech, Inc. Sponsor	Phase 1 Phase
NCT03448042 GO40311 Trial Identifiers	

Eligibility Criteria:

Gender All	Age # 18 Years	Healthy Volunteers No
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Inclusion Criteria:

- Eastern Cooperative Oncology Group (ECOG) Performance Status of 0 or 1
- Life expectancy of at least 12 weeks
- Adequate hematologic and end-organ function
- Acute, clinically significant treatment-related toxicity from prior therapy must have resolved to Grade </=1 prior to study entry

- Left Ventricular Ejection Fraction (LVEF) $\geq 50\%$

HER2-Expressing Breast Cancer-Specific Inclusion Criteria

- Locally tested, Human Epidermal Growth Factor Receptor 2 (HER2)-expressing BC
- Locally advanced or metastatic BC that has relapsed or is refractory to established therapies

HER2-Expressing Gastric/Gastroesophageal (GEJ) Cancer-Specific Inclusion Criteria

- Adenocarcinoma of the stomach or GEJ with inoperable locally advanced or recurrent and/or metastatic disease, not amenable to curative therapy
- HER2-expressing tumor (primary tumor or metastasis) as assessed by local lab testing
- HER2-positive gastric/GEJ cancer must have received prior trastuzumab, cisplatin (or carboplatin or oxaliplatin or investigational platinum agent) and 5-fluorouracil (5-FU)/capecitabine

HER2-Positive Solid Tumor Specific Inclusion Criteria

- HER2-positive tumor (primary tumor or metastasis) as assessed by local (non-central) laboratory testing
- Locally advanced, recurrent, or metastatic incurable malignancy that has progressed after at least one available standard therapy; or for whom standard therapy has proven to be ineffective or intolerable, or is considered inappropriate; or for whom a clinical trial of an investigational agent is a recognized standard of care; or for whom a clinical trial of an investigational agent is considered an acceptable treatment option

Exclusion Criteria:

- Pregnant or breastfeeding, or intending to become pregnant during the study or within 140 days after the last dose of runimotamab
- Significant cardiopulmonary dysfunction
- Known clinically significant liver disease
- Positive for acute or chronic Hepatitis B virus (HBV) infection
- Acute or chronic Hepatitis C virus (HCV) infection
- Human Immunodeficiency Virus (HIV) seropositivity
- Poorly controlled Type 2 diabetes mellitus
- History of ventricular dysrhythmias or risk factors for ventricular dysrhythmias
- Current treatment with medications that are well known to prolong the Q-wave/T-wave (QT) interval
- Known clinically significant liver disease
- Primary central nervous system (CNS) malignancy, untreated CNS metastases, or active CNS metastases (progressing or requiring corticosteroids for symptomatic control)
- Leptomeningeal disease
- Spinal cord compression that has not definitively treated with surgery and/or radiation
- History of autoimmune disease
- Prior allogeneic stem cell or solid organ transplantation