ForPatients
by Roche

Healthy VolunteersAsthma

A Study to Investigate the Safety, Pharmacokinetics, and Immunogenicity of BITS7201A in Healthy Volunteers and Participants With Mild Atopic Asthma

Trial Status	Trial Runs In	Trial Identifier
Completed	1 Country	NCT02748642 GB30030

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 I, Randomized, Observer-Blinded, Placebo-Controlled, Single and Multiple Ascending-Dose Study to Investigate the Safety, Pharmacokinetics, and Immunogenecity of BITS7201A in Healthy Volunteers and Patients With Mild Atopic Asthma

Trial Summary:

This randomized, observer-blinded, placebo-controlled, single and multiple ascending-dose study will be conducted in two parts to evaluate the safety, pharmacokinetics, and immunogenicity of BITS7201A. Part A will be an ascending, single-dose, sequential-group study where participants will be randomly assigned to active drug or placebo. Part B will be an ascending, multiple-dose, sequential-group study where participants will be randomized to active drug or placebo. Total length of the study is anticipated to be approximately 12 months.

Genentech, Inc.
Sponsor

Phase 1
Phase

NCT02748642 GB30030
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	# 18 Years & # 65 Years	Accepts Healthy Volunteers

Inclusion Criteria:

General Inclusion Criteria:

- Body mass index between 18 and 37 kilograms per meter square (kg/m^2)
- Weight 50-120 kilograms
- Participants in good health, determined by no clinically significant findings from medical history, 12-lead electrocardiogram (ECG), and vital signs
- Clinical laboratory evaluations should be within the reference range for the test laboratory unless deemed not clinically significant by the Investigator and Sponsor.
- For women of childbearing potential: agreement to remain abstinent (refrain from heterosexual intercourse) or use a highly effective contraceptive method for at least 70 days after the last dose of study drug
- For men: agreement to remain abstinent (refrain from heterosexual intercourse) or use contraceptive measures, and agreement to refrain from donating sperm for at least 70 days after the last dose of study drug

Additional Inclusion Criteria for Participants With Mild Atopic Asthma:

- Diagnosis of asthma for greater than or equal to (>/=) 3 months prior to screening
- History of atopy
- Pre-bronchodilator forced expiratory volume in 1 second (FEV1) >/=60 percent (%) predicted at screening
- Fractional exhaled nitric oxide (FeNO) >/=30 parts per billion (ppb) at screening and at randomization (predose)

Exclusion Criteria:

General Exclusion Criteria:

- History or clinical manifestations of significant metabolic, hepatic, renal, pulmonary, cardiovascular, gastrointestinal, urologic, neurologic, or psychiatric disorders
- History of hematologic or immunosuppressive disorders
- History of severe depression or suicidal ideation
- History of inflammatory bowel disease
- History of anaphylaxis, hypersensitivity, or significant drug allergies
- History or presence of an abnormal ECG, which is clinically significant
- History of a positive tuberculin skin test in participants who are Bacille Calmette-Guérin (BCG) vaccine naïve or history of a positive interferon-gamma release assay in participants who have received the BCG vaccine
- Participants with neutropenia or thrombocytopenia
- History of alcoholism or drug addiction within 1 year of screening
- Self-reported history of smoking (tobacco, marijuana, or vaping) within the 7 days prior to initiation of study drug
- Smokers not able to pass the tobacco-related laboratory screening and who cannot refrain from smoking during the confinement periods
- Pregnancy or lactation
- History of malignancy, except completely excised basal cell carcinoma or squamous cell carcinoma of the skin
- Any severe bacterial, fungal, or parasitic infections associated with hospitalization or IV antibiotics within 1 year of screening
- History of active parasitic infection within 6 months or exposure to water-born parasites within 6 weeks prior to initiation of study drug

- Upper or lower respiratory tract infection within 4 weeks prior to screening
- Received oral antibiotics within 4 weeks prior to initiation of study drug, or IV/intramuscular (IM) antibiotics within 8 weeks prior to initiation of study drug
- For health volunteers: use of any prescription medications/products within 7 days prior to Day 1 and throughout the study
- Use of any immunosuppressive medication within 30 days or 5 half-lives, whichever is greater, prior to initiation of study drug
- Use of a non-biologic investigational drug or participation in an investigational study with a non-biologic drug within 30 days prior to initiation of study drug (or within 5 half-lives of the investigational product, whichever is greater)
- Use of a biologic investigational therapy or participation in an investigational study involving biologic therapy within 3 months or 5 half-lives, whichever is greater, prior to initiation of study drug
- Received live or attenuated vaccine within 30 days prior to screening
- Received killed vaccine within 14 days prior to initiation of study drug, unless deemed acceptable by the investigator and Sponsor
- Positive blood test for chronic viral infections by: hepatitis B surface antigen, hepatitis C virus antibody, or human immunodeficiency virus (HIV) antibody

Additional Exclusion Criteria for Participants With Mild Atopic Asthma:

- Poorly controlled asthma
- Use of any prescription medications and/or products other than asthma and/or allergic rhinitis medications within 7 days prior to Day 1 and throughout the study, unless deemed acceptable by the investigator and Sponsor
- Active lung disease other than asthma
- Occupations with potential exposure to exogenous sources of nitrous oxide and/or associated with elevated FeNO
- Unable to perform FeNO measurement