ForPatients
by Roche

Asthma

A study to compare different doses of MSTT1041A with a “placebo” – in patients with severe asthma

A Study to Assess the Efficacy and Safety of MSTT1041A in Participants With Uncontrolled Severe Asthma

Trial Status	Trial Runs In	Trial Identifier
Completed	15 Countries	NCT02918019 2016-001549-13 GB39242

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 IIb, Randomized, Double-Blind, Placebo-Controlled, Multicenter, Dose-Ranging Study to Assess the Efficacy and Safety of MSTT1041A in Patients With Uncontrolled Severe Asthma

Trial Summary:

This is a Phase IIb, randomized, placebo-controlled, double-blind, multicenter, multi-arm study which will evaluate efficacy, safety, and pharmacokinetic of MSTT1041A compared with placebo as add-on therapy in participants with severe, uncontrolled asthma who are receiving medium- or high-dose inhaled corticosteroid (ICS) therapy and at least one of the following additional controller medications: long-acting beta-agonists (LABA), leukotriene modifier (LTM), long-acting muscarinic antagonist (LAMA), or long-acting theophylline preparation. The total duration of this study for each participant is approximately 70 weeks including screening, run-in, treatment, and follow-up.

Hoffmann-La Roche
Sponsor

Phase 2
Phase

NCT02918019 2016-001549-13 GB39242
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	#18 Years & # 75 Years	No

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This clinical trial was done to study a new medicine called, “MSTT1041A”, for the treatment of patients with severe asthma. This study was done to find the dose of MSTT1041A that was effective for reducing the number of asthma exacerbations. Other questions that researchers had included finding the dose of MSTT1041A that was effective for improving other symptoms for asthma patients; time it took for MSTT1041A to be distributed in the body; whether MSTT1041A was safe for asthma patients; and whether MSTT1041A caused the immune system to make antibodies against this medicine. There were 502 patients with asthma who took part in this study at 182 study centers in 15 countries.

Inclusion Criteria:

- Body mass index (BMI) of 18 to 38 kilogram/square meter (kg/m^2) and weight >= 40 kg at screening
- Documented physician-diagnosed asthma
- On high dose inhaled corticosteroid (ICS) therapy plus at least one additional allowed controller medication
- Forced expiratory volume in 1 second (FEV1) of 40% to 80% of predicted
- Evidence of uncontrolled asthma
- Use of contraceptive measures

Exclusion Criteria:

- Diagnosis of mimics of asthma
- Diagnosis of occupational asthma, aspirin-sensitive asthma, asthma chronic obstructive pulmonary disease overlap syndrome, or bronchiolitis, as determined by the investigator
- Pregnant or lactating, or intending to become pregnant during the study or within 20 weeks after the last dose of MSTT1041A
- Recent history of smoking
- History or evidence of substance abuse that would pose a risk to participants safety, interfere with the conduct of the study, have an impact on the study results
- Asthma exacerbation within 4 weeks prior to screening
- Intubation for respiratory failure due to asthma within 12 months prior to screening
- Comorbid conditions that may interfere with evaluation of investigational medicinal product
- Known sensitivity to any of the active substances or their excipients to be administered during dosing
- Positive pregnancy test