ForPatients
by Roche

Asthma

A study to find out if a new medicine – MTPS9579A – works in people with asthma

A Study to Evaluate the Efficacy, Safety, and Pharmacokinetics of MTPS9579A in Patients With Asthma Requiring Inhaled Corticosteroids and a Second Controller

Trial Status	Trial Runs In	Trial Identifier
Completed	5 Countries	NCT04092582 2019-000795-41 GB41149

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 IIa, Multicenter, Randomized, Placebo-Controlled, Double-Blind Study to Evaluate the Efficacy, Safety, and Pharmacokinetics of MTPS9579A in Patients With Asthma Requiring Inhaled Corticosteroids and a Second Controller

Trial Summary:

This clinical trial was done to study a new medicine called, MTPS9579A, for the treatment of asthma. This study investigated whether MTPS9579A was effective for controlling asthma in people who used inhaled corticosteroids (ICS) and another medicine – a second controller for the asthma. This was a Phase 2a, multicenter, randomized, placebo-controlled, double-blind study, conducted at 26 study centers in 5 countries.

Genentech, Inc. (A part of F. Hoffmann-La Roche Ltd., Switzerland)	Phase 2a
Sponsor	Phase

NCT04092582 2019-000795-41 GB41149
Trial Identifiers

Eligibility Criteria:

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

Inclusion Criteria:

- Documented physician-diagnosed asthma for at least 12 months prior to screening
- Treatment with asthma controller therapy (daily ICS [fluticasone propionate or equivalent] and at least one additional controller therapy [LABA, LAMA, LTM/LTRA]) for >= 3 months prior to screening, with no changes within 4 weeks prior to screening or during the screening period and no anticipated changes in controller dosing regimens throughout the study
- Documented history of >= 2 asthma exacerbation within the 12 months prior to screening while on daily ICS maintenance therapy
- For women of childbearing potential: agreement to remain abstinent or use contraception For men: agreement to remain abstinent or use a condom, and agreement to refrain from donating sperm

Exclusion Criteria:

- History or evidence of vocal cord dysfunction, reactive airways dysfunction syndrome, hyperventilation associated with panic attacks, or other mimics of asthma
- History or evidence of significant respiratory disease other than asthma, including occupational asthma, aspirin-sensitive asthma, asthma-chronic obstructive pulmonary disease (COPD) overlap syndrome, bronchiolitis, interstitial lung disease, or COPD
- Current smoker, electronic cigarette (e-cigarette) user, former smoker with smoking history of > 10 pack-years, former e-cigarette user with an e-cigarette history of at least daily use for >=10 years, or unwilling to abstain from smoking and/or e-cigarette use from the time of consent through the completion of the study
- History or evidence of any clinically significant medical condition/disease or abnormalities in laboratory tests that, in the investigator's judgment, precludes the patient's safe participation and completion of the study, or interferes with the conduct and interpretation of the study
- Active malignancy or history of malignancy within 5 years of screening, except for appropriately treated non-melanoma skin carcinoma, cervical carcinoma in situ, breast ductal carcinoma in situ, or Stage I uterine cancer
- Pregnant or breastfeeding, or intending to become pregnant during the study or within 60 days after the final dose of MTPS9579A
- Positive for TB at screening