

Asthma

Eine Studie zur Beurteilung der Wirksamkeit, Sicherheit und Pharmakokinetik von MTPS9579A bei Patient*innen mit Asthma, die inhalative Kortikosteroide und eine zweite Kontrollmedikation benötigen

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

Trial Status
Abgeschlossen

Trial Runs In
5 Countries

Trial Identifier
NCT04092582 2019-000795-41
GB41149

Die Informationen stammen direkt von Websites öffentlicher Register wie ClinicalTrials.gov, EuClinicalTrials.eu, ISRCTN.com usw. und wurden nicht modifiziert.

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 is a Phase IIa, randomized, placebo-controlled, double-blind, multicenter, two-arm study to evaluate the efficacy, safety, and pharmacokinetics of MTPS9579A as an add-on therapy in patients with uncontrolled moderate to severe asthma who are receiving daily ICS therapy and at least one of the following additional controller medications: long-acting beta-agonist (LABA), leukotriene modulator (leukotriene modifier [LTM] or leukotriene receptor antagonist [LTRA]), long-acting muscarinic antagonist (LAMA), or long-acting theophylline preparation.

Genentech, Inc.
Sponsor

Phase 2
Phase

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Trial Identifiers

Eligibility Criteria:

Gender

Age

Healthy Volunteers

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