A 24-week Prospective, Open-label, Multicenter, Single-arm rPMS Study in Real-world Setting for Atectura®

Last Update: Jan 14, 2025
A 24-week Prospective, Open-label, Multicenter, Single-arm Regulatory Post-Marketing Surveillance (rPMS) Study in Real-world Setting (Mandatory by Local HA Regulation) for Atectura® (QMF149 150/80 µg o.d., QMF149 150/160 µg o.d. and QMF149 150/320 µg o.d. Via Breezhaler)
ClinicalTrials.gov Identifier:
NCT05217810
Novartis Reference Number:CQMF149EKR01
See if you Pre-qualify
All compounds are either investigational or being studied for (a) new use(s). Efficacy and safety have not been established. There is no guarantee that they will become commercially available for the use(s) under investigation.

Study Description

This surveillance was designed as a prospective, open-label, multicenter, single-arm, non-interventional, observational study to evaluate the safety and effectiveness of Atectura inhalation capsule for up to 24 weeks under routine clinical practice. The three different doses of Atectura inhalation capsule via Breezhaler will be prescribed according to the approved label information in Korea, and the investigation for any additional diagnostic or monitoring will be not conducted for this study

Condition
Asthma
Overall Status
Recruiting
Number of Participants
600
Start Date
May 09, 2022
Completion Date
Dec 23, 2026
Gender
All
Age(s)
12 Years - 100 Years (Child, Adult, Older Adult)

Interventions

Other

Atectura inhalation capsule (150/160ug)

There is no treatment allocation. Patients administered Atectura by prescription that have started before inclusion of the patient into the study will be enrolled.
Other

Atectura inhalation capsule (150/320ug)

There is no treatment allocation. Patients administered Atectura by prescription that have started before inclusion of the patient into the study will be enrolled.
Other

Atectura inhalation capsule (150/80ug)

There is no treatment allocation. Patients administered Atectura by prescription that have started before inclusion of the patient into the study will be enrolled.

Eligibility Criteria

Inclusion Criteria:

1. Adolescent (≥12 years of age) and adult patients with a physician's diagnosis of asthma, who are prescribed Atectura inhalation capsule (indacaterol acetate/mometasone furoate; 150/80, 150/160, 150/320 µg) via Breezhaler, as per the approved label information
2. Patients who participate in the study after signing the consent form for data collection and use (Data Privacy ICF) after receiving a clear explanation of the objectives and nature of the study from the investigator (For patients under the age of 18, consent and signature of a legal representative is required)

Exclusion Criteria:

1. Patients who are contraindicated for this medicinal product as described in the Precautions for Use in the label information (package insert) A. Patients with hypersensitivity reaction to this medicinal product or any of its constituents B. Because this medicinal product contains lactose, patients with hereditary problems of galactose intolerance, the Lapp lactose deficiency or glucose-galactose malabsorption, etc.
2. Patients with acute asthma symptoms, including acute episodes of bronchospasm, for which a short-acting bronchodilator is required
3. Patients participating in other interventional clinical trials

Korea, Republic of

Novartis Investigative Site

Recruiting

Daegu,Dalseo Gu,42602,Korea, Republic of

Worldwide Contacts

If the location of your choosing does not feature any contact detail, please reach out using the information below.

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Source URL: *https://prod1.novartis.com/clinicaltrials/study/nct05217810*

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