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A Study to Evaluate the Efficacy and Safety of QMF149 (Indacaterol Acetate/Mometasone Furoate) Versus Budesonide in Children From 6 to Less Than 12 Years of Age With Asthma

Last Update: Apr 17, 2025
Double-blind, Randomized, Active-controlled, Two-way Cross-over Study, With 12-week Treatment Duration Per Period, to Evaluate the Efficacy and Safety of QMF149 (Indacaterol Acetate / Mometasone Furoate) Compared to Budesonide in Children From 6 to Less Than 12 Years of Age With Asthma
ClinicalTrials.gov Identifier:
NCT05562466
Novartis Reference Number:CQMF149G2301
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

The purpose of this study is to evaluate the superiority in terms of efficacy and evaluate the safety of QMF149 (indacaterol (acetate) / mometasone (furoate)) compared to budesonide in children from 6 to less than 12 years of age with asthma.

* The study duration will be up to 37 weeks including an investigational treatment duration of 12 weeks and a comparator treatment duration of 12 weeks.
* The visit frequency will be 3 weeks for screening, run-in and wash-out period, 6 weeks interval for visits during each treatment period, 30 days for safety follow-up. This is a double-blind, randomized, active controlled, 2 period, 2 treatment (12 weeks duration each) cross-over multi-center study to evaluate the efficacy and safety of indacaterol (acetate)/ mometasone (furoate) compared to budesonide in terms of superiority in children from 6 to less than 12 years of age with asthma with FEV1 ≥50% of the predicted normal value for the participant.

The study duration of 37 weeks includes:

* a screening period of up to 3 weeks
* a run-in period of 3 weeks (run-in medication: Fluticasone propionate 50µg bid)
* a first treatment period of 12 weeks (either with QMF149 75/40µg o.d or budesonide 200 µg o.d via Breezhaler)
* a wash out period of 3 weeks (wash-out medication: Fluticasone propionate 50µg bid)
* a second treatment period of 12 weeks (cross over of the 2 treatment groups with either QMF149 75/40µg o.d or budesonide 200 µg o.d via Breezhaler)
* a safety follow-up period of 4 weeks during which the patient will be back on standard of care treatment as appropriate At the completion of the follow-up period, patient's safety information as well as survival status will

be collected.

Condition
Asthma
Phase
Phase3
Overall Status
Recruiting
Number of Participants
200
Start Date
May 11, 2023
Completion Date
Aug 28, 2028
Gender
All
Age(s)
6 Years - 11 Years (Child)

Interventions

Drug

Budesonide

Budesonide 200 µg o.d via Breezhaler
Drug

QMF149

QMF149 75/40 µg o.d via Breezhaler

Eligibility Criteria

Inclusion Criteria

1. Male or female children ≥ 6 years and \<12 years in age at randomization.
2. Parents/legal guardian must be willing and able to attend study visits and assist the child with the procedures outlined in the protocol (e.g. compliance with taking study medication and completing the diary) ((≥ 70% during the last 14 days of the Run-in period)).
3. Confirmed/documented diagnosis of asthma, as defined by national or international asthma guidelines for at least 12 months prior to study enrollment.
4. Written and signed informed consent by parent(s)/legal guardian(s) for the pediatric patient and assent by the pediatric patient (depending on local requirements) must be obtained before any study-specific assessment is performed.
5. Patient receiving daily treatment of stable low dose ICS alone (i.e. up to 100ug daily dose of fluticasone propionate DPI or equivalent) without additional controller OR low dose ICS (up to 100ug daily dose of fluticasone propionate DPI or equivalent) with one additional controller prior to starting run-in and eligible after run-in on mono ICS alone (fluticasone 100ug/day) for at least 3 weeks (run-in period) prior to randomization.

6. All patients must be symptomatic at randomization (Visit 30), as defined by ACQ-IA≥1.5. Patients previously on low dose ICS may be included for run-in only if ACQ-IA score ≥1.5 at Visit 20 and will be randomized if ACQ-IA score ≥1.5 at Visit 30.

Patients previously on low dose ICS with one controller may do the wash out of the controller before the start of run-in and be included for run-in only if ACQ-IA score ≥ 1 and \<1.5 at Visit 20 and will be randomized if ACQ-IA score ≥1.5 at Visit 30.
7. Pre-Bronchodilator FEV1 ≥50% of predicted normal at start of Run-in (Visit 20) and end of Run-in (Visit 30).

Withholding period of bronchodilators prior to spirometry at all time:

SABA for ≥ 6 hours. For loose combinations of ICS/LABA* a wash-out of ≥ 48 hours before Visit 20 is required (14 days for once daily combinations, i.e. indacaterol), short acting anticholinergic (SAMA) for ≥ 8 hours and xanthines ≥7 days.

* In case of combination ICS/LABA at screening, ICS alone should be continued. Wash-out period of each drug should be adhered to as above and should not be longer. If wash-out period is considered to be longer, please contact the Novartis Medical Monitor.

A one-time repeat of percent predicted FEV1 (pre-bronchodilator FEV1) within 5 days of the Visit is allowed at Visit 20 as well as Visit 30. That would provide sufficient time to receive confirmation from the spirometry data central reviewer of the validity of the assessment. At Visit 20, the Run-in medication should be dispensed only once the repeat spirometry was qualified, and if all inclusion criteria at Visit 20 are successfully met.

If patient fails to meet the pre FEV1 criteria for technical reasons, a rescreen is allowed once and in this circumstance, patients are not required to go back on prior medication (low dose ICS with or without controller) for the full 4 weeks duration and the rescreen can be scheduled at site's convenience. In this case all assessments must be done according to protocol's requirements.
8. FEV1 bronchodilator responsiveness testing using up to 4 puffs of SABA (up to 400µg salbutamol or 360µg albuterol) at Run-in Visit (Visit 20): increase \> and/or = 12% (performed according to ATS/ERS 2019 guidelines). All patients must perform a bronchodilator responsiveness test at start of Run-in. If responsiveness is not demonstrated at Run-in, it may be repeated once on the same day. If responsiveness is still not demonstrated after repeat, documentation of historical reversibility is accepted. If not available patients must be screen failed. Spacers may be used for bronchodilator responsiveness testing.
9. Demonstrate acceptable inhaler use technique with Breezhaler® at randomization, as well as acceptable use of other study devices and be able to complete spirometry procedures.
10. A parent/legal guardian is to complete all e-Diary entries and attend all clinic visits with the patient. It is recommended, if possible, to have the same parent/legal guardian to complete the e-diary entries and attend clinic visits with the patient.
11. Have a documented negative COVID-19 test (validated PCR or antigenic test)) within 3 days prior to randomization visit.
12. For optional Pharmacokinetics (PK) analysis: Participants willing to participate in the optional PK analysis will need to weigh at least 25 kg at screening.

Exclusion Criteria Participants meeting any of the following criteria are not eligible for inclusion in this study.

1. Prior intubation for asthma.
2. Patients who have had a severe asthma exacerbation requiring in the previous month either systemic steroids or hospitalization due to asthma (\>24h) or emergency room visit (≤24 hours).
3. Subjects receiving any medications in the classes specified in Table 6 6 unless they undergo the required washout period prior to Treatment Visit (Day 1) and follow the adjustment through the treatment period.

4. Use of other investigational drugs within 5 half-lives of enrollment, or within 30 days, whichever is longer.
5. History of malignancy of any organ system (other than localized basal cell carcinoma of the skin or in situ cervical cancer), treated or untreated, within the past 5 years prior to screening, regardless of whether there is evidence of local recurrence or metastases.
6. History or presence of impaired renal function as indicated by clinically significant abnormal creatinine or blood urea nitrogen (BUN) and/or urea values, or abnormal urinary constituents (e.g. albuminuria) according to investigator's judgement.

* Evidence of urinary obstruction, or difficulty in voiding
* Evidence of congenital renal abnormalities with an established effect on renal function
* Calculated eGFR \<60 mL/min/1.73m2 using the Bedside Schwartz formula.
7. Patients who have had a respiratory tract infection as determined by the investigator within 4 weeks prior to Visit 1, or between Visit 1 and Visit 30.

Patients may be re-screened once, 4 weeks after recovery from their respiratory tract infection.
8. Any chronic condition of the respiratory tract which in the opinion of the investigator may interfere with study evaluation or optimal participation in the study.
9. Patient with evidence upon visual inspection (laboratory culture not required) of clinically significant (upon the opinion of the investigator) oropharyngeal candidiasis at Visit 30 or earlier, with or without treatment, Patients may be rescreened once their candidiasis has been treated and has resolved.
10. History of chronic lung disease other than asthma such as and not limited to, sarcoidosis interstitial lung disease, cystic fibrosis, mycobacterial or other infection (including active tuberculosis or atypical mycobacterial disease), chronic obstructive pulmonary disease (COPD) and asthma/COPD overlap syndrome (ACOS).
11. Patients with a history of long QT syndrome or whose corrected QT interval (QTc) measured at start of Run-in or Baseline (Fridericia method) is prolonged (≥ 450 msec for boys and girls) and confirmed by a central assessor (these patients should not be rescreened).
12. Subjects who have a clinically significant ECG abnormality reported before Visit 30 (End of Run-in).
13. Subjects who have a clinically significant abnormal laboratory values as per investigator judgement or abnormal liver chemistry results (i.e. ALT, AST, total bilirubin, alkaline phosphatase, GGT and albumin above the upper limit of normal) reported before Visit 30 (End of Run-in).
14. Any surgical or medical condition which might significantly alter the absorption, distribution, metabolism, or excretion of drugs, or which may jeopardize the subject in case of participation in the study.
15. Subjects who, in the opinion of the investigator, are not able to be compliant with study treatment or who have any medical or mental disorder, situation, or diagnosis which could interfere with the proper completion of the protocol requirements or risk the subject's safety while participating in the study.
16. Subject is an immediate family member of the participating investigator, sub-investigator, study coordinator, or employee of the participating investigator.
17. Patients who have been treated with long-acting theophylline preparations within four weeks prior to Screening and/or during the screening period or who have been treated with short-acting theophylline preparations within two weeks prior to Screening.
18. Patients who have been treated with non-approved and according to international guidelines not recommended experimental drugs for routine asthma therapy within four weeks prior to Visit 1 and/or during the screening period.
19. Use of Long-Acting Muscarinic Antagonist (LAMA) as maintenance treatment within 3 months prior to Screening.
20. Evidence of unstable disease within 4 weeks prior to Screening (Visit 1) that in the opinion of the investigator would put the safety of the subject at risk through study participation or would confound the interpretation of the results if the condition/disease exacerbated during the study.
21. History of hypersensitivity to any ingredients of the study drugs including fluticasone propionate,

indacaterol acetate, mometasone furoate, budesonide and salmeterol/albuterol or drug of similar chemical classes. This includes any known hypersensitivity or intolerance to the excipients, including lactose.
22. Patients with Type I diabetes or uncontrolled Type II diabetes either by HBA1c\>8 or as per judgement of investigator prior to End of Run-In (Visit 30)
23. Patients receiving any asthma-related or non asthma-related prohibited medications as specified in the protocol.
24. Immunotherapy or desensitization for allergies started within 3 months prior to Visit 20, or where the maintenance dose is expected to change during the study.
25. Female patients of childbearing potential defined as all females physiologically capable of becoming pregnant (including female pediatric patients who are menarchal or who become menarchal during the study)) who do not agree to abstinence or, if sexually active, do not agree to the use of contraception as defined in the exclusion criteria.

Effective contraception methods include:

* Total abstinence (when this is in line with the preferred and usual lifestyle of the subject. Periodic abstinence (e.g., calendar, ovulation, symptothermal, post-ovulation methods) and withdrawal are not acceptable methods of contraception
* Barrier methods of contraception: Condom or Occlusive cap (diaphragm or cervical/vault caps). For UK: with spermicidal foam/gel/film/cream/ vaginal suppository
* Use of oral, (estrogen and progesterone), injected or implanted hormonal methods of contraception or other forms of hormonal contraception that have comparable efficacy (failure rate \<1%), for example hormone vaginal ring or transdermal hormone contraception or placement of an intrauterine device (IUD) or intrauterine system (IUS) If using oral contraception females should have been stable on the same pill for a minimum of 3 months before taking investigational drug. The decision on the contraceptive method should be reviewed at least every 3 months to evaluate the individual need and compatibility of the method chosen.

Argentina

Novartis Investigative Site

Recruiting

Mendoza,5500,Argentina

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Recruiting

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