Desiree Silva

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Joondalup

WA 6027

Clinical Trials 0455522238

Dear Belinda,

My office is participating in a new clinical trial called the ARIA study, a phase 3 study to evaluate the efficacy, safety and tolerability of an investigational drug called fluticasone furoate/umeclidinium bromide/vilanterol trifenatate (FF/UMEC/VI) in adolescents with asthma. To qualify for this study, participants must be 12 to 17 years of age (inclusive) with inadequately controlled asthma despite requiring therapy with inhaled corticosteroids (ICS)/long-acting beta2-agonists (LABA).

The fixed-dose triple combination of FF/UMEC/VI, delivered via the Ellipta dry-powder inhaler (DPI), has been approved in the United States (US), Japan, Australia, Canada and several other countries as the first once-daily single-inhaler triple-therapy (SITT) device for the maintenance treatment of asthma in adults aged 18 years and older. The ARIA study aims to provide important information on whether the favourable profile of FF/UMEC/VI Ellipta demonstrated in adult asthma patients extends to the adolescent age group.

ARIA is a multicentre, active-controlled, double-blind, parallel-group study. Approximately 1,000 individuals will be screened to achieve 292 participants randomly assigned to the study intervention as follows:

* Individuals who meet all the eligibility criteria at screening will enter the run-in period for approximately 4 weeks to continue study eligibility assessments. All participants will be provided with fixed-dose ICS/LABA to take once a day during this period and rescue medication (albuterol/salbutamol) to use on an as-needed basis throughout the study
* Following the run-in period, participants who meet the randomisation criteria will be randomised 1:1 in a double-blind manner to take FF/UMEC/VI once daily (QD) or FF/VI QD, both self-administered via the Ellipta DPI for the 24-week study treatment period
* A safety follow-up telemedicine or clinic visit will be conducted approximately 7 days after the study treatment period

To pre-qualify for this study, a patient must:

* Be 12 to 17 years of age (inclusive) with a clinical diagnosis of asthma for at least 1 year
* Have required daily ICS/LABA treatment for at least 12 weeks with no changes to maintenance asthma medications during the past 6 weeks
* In the past year, have either a documented healthcare contact for acute asthma symptoms or documented temporary change in asthma therapy for acute asthma symptoms
* Have inadequately controlled asthma (Asthma Control Questionnaire [ACQ]-6 score ≥1.5), despite ICS/LABA maintenance therapy

This is not a complete list of eligibility criteria. The study protocol will provide all inclusion and exclusion criteria. The study sponsor, GSK, is committed to ensuring clinical study participants are representative of the population affected by asthma.

ARIA study enrolment is currently active and visits are conducted at my research location. There will be no charge to study participants for their participation in this study. The investigational drug, study-related procedures and study visits will be provided at no charge.

If you have a patient you think may qualify, please call my office on the number below. When referring a patient to this study, please be assured that our involvement will be strictly study-related and the primary care of the patient will remain unchanged.

If you have questions about the ARIA study, please do not hesitate to contact my office. Thank you for your consideration.

Sincerely,

[Desiree Silva]

Principal Investigator

**Study coordinator:** Danita Kapp

**Phone number: 0455-522-238**