

# The FORCE2 Study: A Breath of Fresh Air!

If you have asthma and are considering your treatment options, you might be interested in joining the **FORCE2 Study**.



We are looking for adults who:

- **have been diagnosed with asthma for at least 1 year**
- **developed asthma before the age of 40 years**
- **are currently being treated with inhaled steroids**

There are other criteria that must be met before you can take part in the **FORCE2 Study**. The study team will discuss these with you.

For further information about the **FORCE2 Study**, please contact:

Contact person: .....

Study center: .....

Address: .....

.....

Telephone: .....

Email: .....

*Contacting us does not mean that you must join the **FORCE2 Study** or that you will be able to participate. Your participation is entirely voluntary, and you can withdraw from the study at any time if you change your mind. There will be no charge for any study-related treatment or care. Some, but not all, of the risks and benefits of the investigational drugs are known.*



# NOW ENROLLING: A CLINICAL RESEARCH STUDY FOR ADULTS WITH ASTHMA ON MEDIUM OR HIGH-DOSE OF INHALED CORTICOSTEROIDS



The **FORCE2 Study** is a clinical research study in adults with asthma who are on medium or high-dose inhaled corticosteroids. Participants will be in the study for approximately 16 weeks.

## Key objective of the FORCE2 Study

- To demonstrate the superiority of **CHF 1535** pMDI (fixed combination of extrafine beclomethasone dipropionate 200µg plus formoterol fumarate 6µg) compared to **CHF 718** pMDI (extrafine beclomethasone dipropionate 100µg) in terms of change from baseline in  $FEV_1$  AUC<sub>0-12h</sub> at Week 12.



## Key eligibility criteria for participants enrolling in the FORCE2 Study:

- Male or female aged  $\geq 18$  and  $\leq 75$  years.
- A documented history of asthma for at least 1 year, with an onset before the age of 40.
- Use of medium-dose inhaled corticosteroids with or without a long-acting  $\beta_2$ -agonist or high-dose inhaled corticosteroids alone for 3 months (at a stable dose for at least 4 weeks prior to screening).
- A pre-bronchodilator  $FEV_1 \geq 40\%$  and  $\leq 85\%$  of predicted, after appropriate washout from bronchodilators, at the screening and randomization visits.
- No history of near-fatal asthma or of a past hospitalization for asthma in an intensive care unit.
- Have not been hospitalized, admitted to the emergency room or used systemic corticosteroids for an asthma exacerbation in the 4 weeks prior to the screening visit or during the run-in period.
- Have not experienced an unresolved respiratory tract infection in the 4 weeks prior to the screening visit or during the run-in period.
- Do not have a documented coronavirus disease 2019 (COVID-19) diagnosis within the last 8 weeks (or complications from this disease) prior to screening.
- On a stable dose of inhaled corticosteroid during the 4 weeks prior to screening.
- Have not used systemic corticosteroid medication in the 4 weeks prior to screening or slow-release corticosteroids in the 12 weeks before screening.
- Are not a current or ex-smoker with a total cumulative exposure equal to/more than 10 pack-years or not have stopped smoking within one year prior to screening visit.



## The FORCE2 Study includes the following:

- A screening/run-in period (2 weeks) – participants will be evaluated to check their eligibility to join the study.
  - During this period, participants on a medium dose ICS/medium dose ICS-LABA prior to the study will be given CHF 718 pMDI (2 inhalations BID) and participants on a high dose ICS prior to the study will be given CHF 718 pMDI (4 inhalations BID).
- A treatment period (12 weeks) – participants will be randomized 1:1 to receive either **CHF 1535** or the reference study medication.
- A follow-up period (1 week) – the investigator/designee will call the participant 1 week after they have received their last dose of study medication (or after the Early Treatment Discontinuation Visit) to check the status of any unresolved AEs and record any new AEs.



If you have any patients who might be interested in and are suitable for referral to the **FORCE2 Study**, please do not hesitate to have them contact me. Thank you very much for your time and consideration.

Contact details:

Name: .....

Telephone number: .....

Email address: .....

