



#### What is the purpose of this study?

The primary purpose of your participation in this study is to help answer the following research question, and not to provide you treatment for your condition:

Determine the effect of the investigational drug on asthma.

Approximately 4000 people will take part in the study.



# What will I be asked to do if I participate in the study?

Participation lasts up to 80 weeks with at least 12 visits.

During these visits, the study staff at the study site will evaluate your health and perform tests including:

- Blood pressure and heart rate measurements
- Blood sample analyses
- Pregnancy tests
- Electrocardiograms (ECGs)
- Physical exams

The study staff will ask you questions about your illness and symptoms.



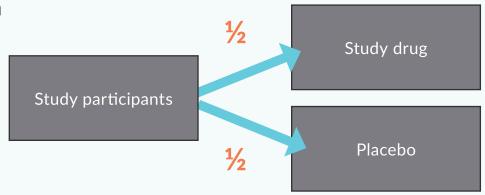
#### About the drug being studied

The study drug is a tablet that you will initially take once daily by mouth. If you tolerate the study drug well, you will later take the tablet twice daily.

You will be randomly placed into one of two study drug groups:

- One group will receive the study drug.
- One group will receive a placebo, which is an inactive pill that looks like the study drug.

You will have a 50% chance of receiving the study drug and a 50% chance of receiving the placebo.





## Are there any possible benefits?

- There's no guarantee that the study drug will improve the symptoms of type 2 diabetes
- There's a chance that you will see no benefit from participating
- The information we receive may help us better treat other patients with type 2 diabetes



## What are the possible risks?

There may be side effects from the study drug, including:

- Dizziness
- Nausea
- Constipation

There may be other side effects — the study staff will review the list with you.

There may be other, unknown side effects of study drug or other risks of study participation.

- Study-related blood tests may cause:
- Bleeding/bruising at puncture site



#### How will my privacy be protected?

All information we gather will stay confidential and will be coded with a number to keep your name a secret

No personal information like your name or contact information will be listed in any reports

The coded information will only be seen by:

- The study team at this site
- The company sponsoring this research study and the sponsor's authorized representatives
- The government groups that approve and monitor this research study



### What does it mean to consent?

Consent is a conversation between you and your study doctor that:

- Explains the details of the study and its possible benefits and risks
- Gives you a chance to ask questions about clinical research and this study

Based on that conversation, you may or may not decide to agree to participate in this study

You can leave the study at any time without loss of rights or benefits you would otherwise have had if you had not agreed to be in this study



## What are the next steps?

Read the informed consent form (ICF)

Make sure all your questions are answered by the study staff

If you choose to participate:

- Sign the informed consent form document
- Complete or schedule your first appointment



WorldPharma appreciates your consideration to taking part in this clinical research study.

