## What can I expect if I take part?

If you do take part, you may be in the study for up to around 3 years. You'll have regular visits with the study doctor and their team, and you'll need to do a few things at home.

We understand the impact COPD has on your daily life, so we want to make it as easy as possible to take part. If the study doctor agrees, you may be able to:

- Have most of your visits from home, through telehealth (video call)
- Get the study treatment delivered to your door at a time that suits you

Between all of your visits, you will always be able to contact the study team with any questions or concerns.

Thank you again for your interest in the **THARROS study.** 

We hope this study may help find treatments to prevent serious heart events in people with COPD.

Study Code D5989C00001 Date: 1-28-2024 Version no.: 2.0 US-enUS

### **Discussion** guide

You've probably got lots of questions.

Before you decide whether to take
part, you might want to ask the study
doctor:

- Will it cost me anything to take part?
- Do I need health insurance?
- Are there any side effects?
- How does the study treatment compare with my current COPD medications?
- ♦ Who will know which study treatment I am taking?
- ◆ Can anyone find out that I'm taking part?
- How will you use my information and data?
- ◆ What if I want to stop taking part?
- ♦ What happens next?

If you have any questions or would like any more information about the THARROS study scan the QR code



Study Code D5989C00001 Date: 1-28-2024 Version no.: 2.0 US-enUS

# What do your COPD & heart health have in common?

# You may be able to find a treatment for both from the comfort of home

THARROS is a clinical study looking at whether treatments for COPD may help prevent COPD flair-ups, heart failure and heart attacks. We understand the impact COPD has on your daily life, so we've made it easy to get involved. You could have most of your visits over video call and get study treatment delivered to your door.



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Have been diagnosed with COPD

Are between 40 and 80 years old

Are a current or former smoker

COPD and heart health are closely linked COPD, especially flare-ups, affects how well the lungs work. When the lungs are not working like they should, it puts a **strain** on the heart. This may lead to a higher risk of **serious heart events** like heart attacks and heart failure. Some people with COPD are also at risk because they smoke, which damages both the airways and the blood vessels.

The THARROS study is looking at whether **current treatments** for COPD may help to prevent these serious heart events.

### About the study treatment

**Budesonide** is a type of treatment called an **inhaled corticosteroid** (ICS). Combination inhalers that include an ICS help to reduce inflammation and prevent COPD flare-ups.

We think they may also help to prevent serious heart events. To help find out, this study will compare the effects of 2 different inhalers on heart health:



This inhaler will also contain the medicines glycopyrronium and formoterol fumarate. It's known as a BGF inhaler, or by the brand names BREZTRI and TRIXEO.

The other group will get an inhaler without budesonide

This inhaler will only contain glycopyrronium and formoterol fumarate. It's known as a GFF inhaler, or by the brand name BEVESPI.

BGF and GFF inhalers are both already approved COPD treatments.

Study Code D5989C00001 Date: 1/28/2024 Version no.: 2.0 US-enUS

### Important things to know



Everyone in this study will:

Get an **approved treatment** for their COPD, with either a BGF or GFF inhaler.

Take the study treatment using an inhaler. There are no treatment injections or infusions.

Have constant access to **rescue inhalers**, to use any time.

If you do join the study, you will switch from your regular COPD medications to the study treatment. This will help keep the results accurate, by making sure everyone is on the same, stable medication. The study team will make sure it is safe for you to switch, and the study doctor will discuss this with you in detail.

### What will happen during visits?

You will have 11 visits in total (around every 3 to 6 months). Each visit will last between 1 and 4 hours, but there are no overnight visits or hospital stays. Most of these visits may be available from home through telehealth (video call).

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