Which study drug will I receive?



If eligible to take part, you will be randomly assigned (like drawing names out of a hat) to one of five study treatment groups:

- **Group 1** tigulixostat highest dose
- Group 2 tigulixostat mid-level dose
- Group 3 tigulixostat lowest dose
- Group 4 allopurinol
- **Group 5** placebo

For every 30 participants receiving tigulixostat (10 people receiving each dose level), 10 will receive allopurinol and 1 will receive placebo. Therefore **you have just over a 2 in 100 chance of being assigned to placebo**. You cannot choose which study drug you will take, and neither you nor the study team will know which study drug you are receiving.

How do I take the study drugs?

All of the study drugs will be taken as **oral tablets/capsules**. You will take the tablets/ capsules at home three times every day, for the duration of the study treatment period.

What will happen at the study center?



If eligible for the **EURELIA 2 Study**, you will be asked to **visit the study center up to 17 times**. At study visits, you will undergo tests to check on your health, and to see how you are responding to your assigned study drug.

You will also be asked to fill out an electronic diary every day to record any gout flare-ups.



GOUT FLARES BREAKING YOUR STRIDE? JOIN OUR RESEARCH!

Study Information Brochure



Do I have to take part?

No. Participation is voluntary. If you decide not to take part, your usual

healthcare will not be affected.

Want to know more?

contact:

Name:

Address:

Telephone:

when you speak to them.

Email:

Study center:

To learn more about the EURELIA 2 Stud

If you do contact the study center, it does not

Thank you for your interest

in the EURELIA 2 Study.

mean that you have to or will be able to take part;

the study team will tell you more about the study



What are clinical research studies?



Clinical research studies are carried out to discover whether an investigational drug:

- ls safe to take
- Mas any side effects
- le Can make you feel better
- Works as well as or better than other drugs

What is the EURELIA 2 Study?



The **EURELIA 2 Study** is designed to evaluate whether a 12-month course of an investigational drug, called **tigulixostat**, can **reduce uric acid levels** for **people with gout and high uric acid levels**.

Three different doses of tigulixostat will be compared with an approved uric acid-lowering medication (**allopurinol**) and with **placebo**. A placebo looks exactly like tigulixostat or allopurinol but contains no active medication.

Why is the EURELIA 2 Study being carried out?



Gout is caused by a **high level of uric acid in the blood**, which builds up over time. Uric acid is produced when the body digests foods that contain a high level of a chemical called purine; purines can be found in certain types of meat, seafood and alcohol. Normally, this uric acid is then passed through the urine. However, in people with gout, uric acid is not eliminated correctly and builds up in joints, causing very small crystals of uric acid to form; these are called **urate crystals**. When urate crystals dissolve, this can trigger a painful gout **flare-up**. Many of the current approved treatments for gout are called urate-lowering therapies (ULTs). These are designed to lower the uric acid levels in blood. However, due to how these treatments work in the body, they can disturb the urate crystals in joints, leading to a gout flare-up.

Who can take part in the EURELIA 2 Study?

Just over **2540 people** are expected to take part in the study at **study centers worldwide**. You may be able to take part in the **EURELIA 2 Study** if you:

- Are aged between 18 and 85 years
- Mave high uric acid levels
- Mave gout or a history of gout

There are other criteria that you will need to meet to qualify, which the study team will discuss with you.

2540

How long will the EURELIA 2 Study last?



The **EURELIA 2 Study** will last for up to **14 months** (less if you are not currently on ULT or if you are assigned to receive placebo) and is made up of the following parts:

Ø Part 1 – Screening

- You will be assessed to see if you can join the study
- Part 2 Wash-out period

(up to 1.5 months, if required):

- You will stop taking any ULT you are currently taking to treat your gout
- You will start taking medication to prevent gout flare-ups, which you will continue to take throughout Part 3
- If you are not taking a ULT when this study begins, you will skip Part 2
- Part 3 Study treatment period (up to 12 months*):
 - You will be randomly assigned to either tigulixostat, allopurinol, or placebo (randomly is like drawing names out of a hat)
 - If you are not taking a ULT when this study begins, you will also begin to take gout flare-up prevention medication in Part 3

* If you are assigned to placebo, Part 3 will last for 6 months.

Follow-up period (0.5 months):

- You will stop taking your study drug and medication to prevent gout flare-ups
- Two weeks later, you will be asked to return to the study center for final health checks
- After completing follow-up you may be able to start an available ULT (advised by the study doctor)