

THE LUMINA-1 STUDY

As you may already know, current treatment options for fibrodysplasia ossificans progressiva (FOP) are limited.

Some medicines can help manage secondary symptoms, such as pain and swelling.

However, to date, there are no approved treatments for FOP itself. That is why we are conducting the LUMINA-1 study – a clinical research study that will find out if an investigational study drug:

- is well-tolerated
- can slow or stop abnormal bone growth (known as heterotopic ossification or 'HO'), seen in people with FOP

The total length of the study is approximately 19 months, including screening and follow-up.

The study consists of two dosing periods, each lasting around 6 months. During the first dosing period, participants will randomly receive either the investigational study drug (50% of participants) or a placebo (50% of participants). A placebo is an inactive substance given in the same way as the investigational study drug so that we can compare the results. During the second dosing period, **all participants** will receive the investigational study drug. This means that all participants will have access to the study drug for at least 6 months during this study.

Both the investigational study drug and the placebo are given as intravenous (IV) infusions (an injection into the vein), once every 4 weeks. Once the treatment periods are over, participants will be required to attend study visits around once every 4 weeks for around 6 months so that we can monitor their health.

To learn more about this study, please ask your doctor to contact the Regeneron Medical Information department at 1-844-MID-REGN (1-844-643-7346) 8 am - 8 pm EST (13:00 – 01:00 GMT) Mon-Fri.

Alternatively, they can visit our website for more information.

We are looking for approximately 40 people who:

- have been diagnosed with FOP
- have the ACVR1 [R206H] gene mutation
- are between 18 and 60 years old

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