

# PATIENT JOURNEY

This tool is to help you understand what to expect during the LUNA 3 study.



## Give consent & confirm study qualification | Screening period

- You must sign the Informed Consent Form (ICF) before you have any study tests or exams.
- After you sign the ICF, you will have tests and exams to find out if you qualify for the study.
- This part of the study is called the Screening period.



## Attend your first study visit & receive study medication or placebo | Blinded period

- You will visit the study doctor's office for tests and exams.
- You will be randomly assigned by a computer to receive either the study medication or placebo.
- This part of the study is called the Blinded period, meaning neither you nor study staff will know if you are assigned study medication or placebo.



## Have weekly blood draws | All periods (except Long-Term Extension)

- You will provide blood samples every week between monthly study visits.
- You may wish to ask the study staff for your blood test results so that you can track your platelet counts.



## Take study medication or placebo & attend monthly visits | Blinded period

- You will take the pills assigned to you at home and attend monthly visits at the study doctor's office for up to 24 weeks (6 months).
- If your platelet counts do not increase, you may be able to start taking the study medication (with no chance of placebo) at Week 13.



## Start or continue taking the study medication & continue monthly visits | Open-Label period

- All patients will take the study medication for at least 28 weeks (7 months). No one will receive placebo.
- You will continue to attend monthly visits at the study doctor's office for 28 weeks.
- This is called the Open-Label period, meaning you and the study staff will know you are taking the study medication.



## Take the study medication for an additional year, if approved | Long-Term Extension period

- After the Open-Label period (28 weeks), you may be asked to participate in an extension of the study in which you take the study medication for an additional year.
- This optional period is called the Long-Term Extension period.



## Attend a follow-up visit | Safety Follow-up period

- Four weeks after you stop taking the study medication, you will have a follow-up visit.
- This will be your last study visit.



LUNA 3

# PATIENT JOURNEY



## 1. GIVE CONSENT & CONFIRM STUDY QUALIFICATION | SCREENING PERIOD

The Informed Consent Form (ICF) (sometimes referred to as the Patient Information Sheet or Assent Form) explains the study and what you can expect in more detail. The study doctor or staff will review the information in the ICF and answer questions you have about the study. It is up to you whether you participate, but you must sign the ICF before you can receive study tests or exams.

After you sign the ICF, you will have tests and exams to find out if you qualify for the study. These include, but are not limited to, the following:

- physical exam and vital signs (blood pressure, heart rate, and temperature)
- heart test
- blood test
- urine test
- bleeding assessment
- questionnaires



## 2. ATTEND YOUR FIRST STUDY VISIT & RECEIVE STUDY MEDICATION OR PLACEBO | BLINDED PERIOD

You will visit the study doctor's office to have tests and exams like those you had at Screening.

You will be randomly assigned by a computer to receive either the study medication or placebo, which looks like the study medication, but does not have active ingredients. You will have a 2 in 3 chance of receiving the study medication and a 1 in 3 chance of receiving placebo. This means that for every 2 patients who receive study medication, 1 patient will receive placebo. Because this part of the study is blinded, neither you nor the study staff will know whether the pills you receive are study medication or placebo.



## 3. TAKE STUDY MEDICATION OR PLACEBO & ATTEND MONTHLY VISITS | BLINDED PERIOD

You will take the study medication or placebo (whichever you were assigned) by mouth 2 times per day for up to 24 weeks. At your monthly study visits, you will have study tests and exams like those you had at Screening.

If your platelet counts do not increase during the first 12 weeks of the study, you may have the option to begin taking the study medication (with no chance of receiving placebo) at Week 13. This means you would skip ahead to the Open-Label period of the study in which everyone takes the study medication.

If your platelet counts *do* increase during the first 12 weeks of the study, you will continue taking the pills assigned to you for the full 24 weeks of the Blinded period.



## 4. HAVE WEEKLY BLOOD DRAWS | ALL PERIODS (EXCEPT LONG-TERM EXTENSION)

You will have blood drawn every week between study visits to determine your platelet counts and other blood information. This may be done at the study doctor's office or at home by a healthcare professional (if this service is available where you live). If you would like to receive your blood test results, ask the study staff.



## 5. START OR CONTINUE TAKING THE STUDY MEDICATION & CONTINUE MONTHLY VISITS | OPEN-LABEL PERIOD

After 24 weeks of being in the study (or after 12 weeks if your platelet counts did not increase), everyone will have the opportunity to take the study medication for the next 28 weeks.

You will continue to go to the doctor's office every 4 weeks to have study tests and exams like those you had at Screening and other study visits. You will continue to have weekly blood draws in between study visits.



## 6. TAKE THE STUDY MEDICATION FOR AN ADDITIONAL YEAR, IF APPROVED | LONG-TERM EXTENSION PERIOD

If your study doctor finds that you are benefiting from taking the study medication, you may have the option to participate in the Long-Term Extension (LTE) period. This period will last another 12 months. During this time, you will continue to take the study medication twice daily and visit the study doctor's office every 4 weeks. You will no longer need weekly blood draws between monthly study visits.



## 7. ATTEND A FOLLOW-UP VISIT | SAFETY FOLLOW-UP PERIOD

Four weeks after you stop taking the study medication, you will come to the doctor's office for your last visit so that the doctor or staff can check your health status. You will have the same tests and exams that you had at all other study visits. You will continue to have weekly blood draws in the 4 weeks leading up to your last visit.

