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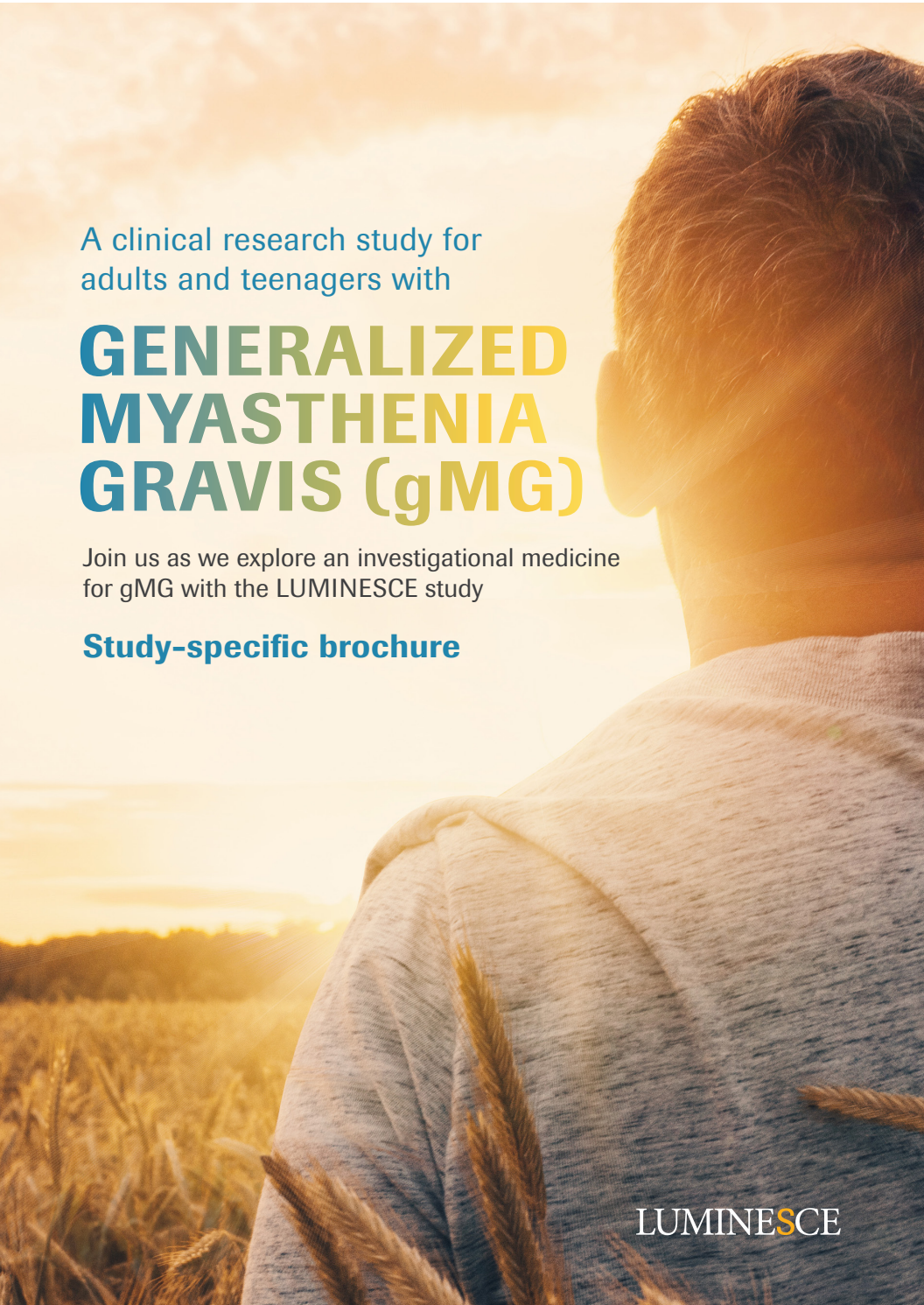


A clinical research study for adults and teenagers with

GENERALIZED MYASTHENIA GRAVIS (gMG)

Join us as we explore an investigational medicine for gMG with the LUMINESCE study

Study-specific brochure

LUMINESCE

Table of contents

About generalized myasthenia gravis

Myasthenia gravis is a rare, chronic, autoimmune condition. It affects how muscles and nerve signals from the brain communicate. When multiple muscle groups in the body are affected, it is known as generalized myasthenia gravis (gMG).

gMG happens when a person's immune system stops working properly. The immune system is meant to help the body overcome sickness by attacking intruders such as bacteria and viruses. The immune system in a person with gMG mistakenly attacks certain proteins in the muscles. Specifically, it attacks those meant to receive nerve signals telling muscles to move or contract. This immune system attack generally affects the area where nerve signals and muscle fibres meet, called the neuromuscular junction (NMJ). This area then becomes damaged and does not work properly. As a result, the nerve signals cannot get through, and the affected muscles, such as the diaphragm (used for breathing) and muscles moving the eyes, face, and limbs, become weak.

Currently, people with gMG have few treatment options aimed at managing symptoms, and these can cause side effects in some people. There is a need to find safer and more effective therapies for those living with gMG.

People with gMG often have symptoms that include:


Change in facial expressions


Drooping eyelids


Double and/or blurred vision


Trouble walking and lifting objects


Shortness of breath


Trouble speaking, chewing, swallowing

Over time, some people may experience changes in the severity of their symptoms.

What is the LUMINESCE study?

LUMINESCE is a global clinical study to test an investigational medicine for people with gMG.

The LUMINESCE study will include about 240 adults and teenagers diagnosed with gMG in approximately 19 countries and will look at how safe and effective satralizumab, the investigational medicine, is for treating their disease. Everyone who takes part in the study will either receive the **investigational medicine (satralizumab) or a placebo** (looks like the investigational medicine but is not a real medicine) **in addition to the gMG medication they are currently receiving**. During the Open-Label period of the study, all participants will receive satralizumab.

What is satralizumab?

Satralizumab is a medicine that works by blocking certain proteins in the body that cause immune system damage.

It is given by **subcutaneous injection** with a needle, just under the skin of the stomach or thigh, **every 4 weeks**. In the LUMINESCE study, study treatment (satralizumab or placebo) will be given at the study center by an appropriately trained member of the study team.

Satralizumab is an investigational medicine, which means it has not yet been approved for the treatment of gMG. Recent clinical studies have found satralizumab to be safe and effective for the treatment of Neuromyelitis Optica Spectrum Disorder (NMOSD). It has been approved for use in NMOSD in many countries across the Americas, Asia, Europe and Australia, and is under review by other Health Authorities worldwide. NMOSD is another autoimmune disorder that is similar to gMG in how the body's immune system attacks tissues of the body. LUMINESCE is exploring whether satralizumab may also work to treat gMG.

Am I eligible to take part in the LUMINESCE study?

You may be eligible to take part in the LUMINESCE study if you:

- ☑ Are at least 12 years of age
- ☑ Have been diagnosed with gMG and have gMG-specific autoantibodies
- ☑ Are currently taking another gMG medication at a stable dose

A **stable dose** means that you have been taking your gMG medication at the same dose and frequency for a specified period of time before entering the study

Antibodies are proteins produced by the immune system that attack foreign invaders such as bacteria and viruses. Some antibodies – known as **autoantibodies – attack the body's own tissues**

If you are interested in joining the LUMINESCE study, then the study doctor will need to look at your medical records to check that you meet the basic study criteria.

It is important to note that even if you meet the basic criteria, the study doctor will still need to do some specific tests during the Screening period to make sure you are eligible to take part.

Please speak with the study doctor if you have any questions about whether you can take part in the LUMINESCE study

What happens if I am eligible?

If you are eligible and interested in taking part in the LUMINESCE study, you will be asked to read and sign an **Informed Consent Form (ICF)** or **Informed Assent Form (IAF).** The ICF is for adults and the IAF is for teenagers.

The ICF/IAF confirms that you understand all the important information about the LUMINESCE study and that you agree to take part voluntarily. You will need to sign this form before any study procedures are performed, including the study screening tests.

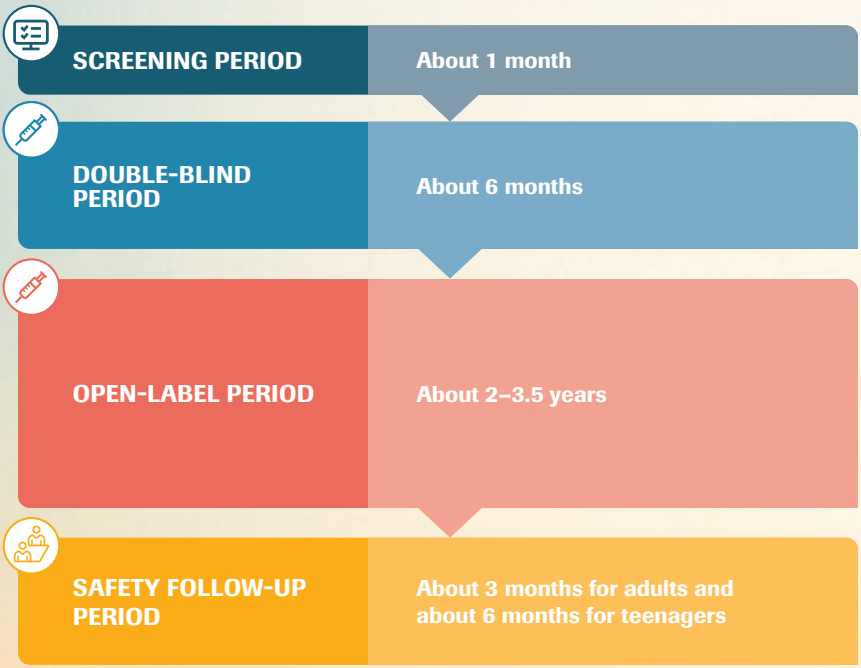
Please take your time and read through the information about the LUMINESCE study and consider discussing it with your family before making your decision. Make sure to review the form with the study team, so that you understand what is involved and your responsibilities if you take part in the study.

If you have any questions, or something in the ICF/IAF is not clear, please let the study doctor know. They will be happy to talk with you and answer any questions.

The ICF and IAF are important legal documents

How long is the LUMINESCE study?

The LUMINESCE study is split into **4 main parts**:



Your total time in the study may be up to **4 years**.

What happens during the Screening period?

If you are interested in taking part in the LUMINESCE study and have signed the ICF/IAF, you will visit the study center to complete some procedures and tests during what is called the **Screening** period.

The results of these tests will determine if you are eligible to join the LUMINESCE study. The procedures and tests include:

- Discuss your medical history
- Medication review
- Complete physical examination, including weight and height measurement
- Vital signs (e.g., blood pressure, heart rate)
- Blood tests
- Urine tests
- Pregnancy test
- Electrocardiogram (ECG)
- Tuberculosis test (may include a chest X-ray or chest CT scan)
- Muscle strength measurements
- Breathing test to see how well your breathing muscles work
- Questionnaires about your disease (e.g., quality of life)

Screening will take approximately 1 month (no more than 6 weeks)

CT, computerized tomography

What happens during the Double-Blind period?

The **Double-Blind** period is when you will receive the study treatment in addition to receiving your current gMG medication. It will last 24 weeks (approximately 6 months). Half of the people taking part will get the investigational medicine (satralizumab) and half will get a placebo.

A placebo appears the same and is given in the same way as the investigational medicine, but it does not contain any medicine. This is a **double-blind period**, meaning that neither you nor the study doctor can choose or know what treatment group you have been assigned to. However, if your safety is at risk, the study doctor can find out which group you are in.

A **placebo** is used as a control in the study to help researchers determine if any changes seen are due to satralizumab. Even though a placebo is being used in this study, everyone will continue to receive their current gMG medication

Participants will be randomly (like flipping a coin) placed into one of two treatment groups:

50%

Group A

satralizumab (the investigational medicine) **in addition to your current gMG medication**

50%

Group B

placebo (an injection that looks like the investigational medicine but is not a real medicine) **in addition to your current gMG medication**

You will have an equal chance (50/50) of being placed in either group. The study treatment will be administered as one or two injections (depending on body weight) under the skin of your stomach or thigh, using a needle. Treatment will occur every 4 weeks (plus an extra dose at Week 2). During this period, there will be 8 scheduled visits to the study center. **Each visit will last about 4–5 hours**; this does not include possible waiting time in between procedures and tests.

Procedures and tests during the **Double-Blind** period are similar to those done in the Screening period.

The Double-Blind period will last about 6 months

What happens during the Open-Label period?

After you have completed the Double-Blind period, you may continue into the **Open-Label** period. During this part of the study, **you will receive satralizumab**, regardless of whether you were in Group A or B during the Double-Blind period.

In the **Open-Label** period, you will receive satralizumab—in addition to your current gMG medication–every 4 weeks for about 2-3.5 years. After Week 24, you may have the **option to receive satralizumab injections at home** if supported by the study doctor.

During this period, if your gMG symptoms are well-managed, you may begin to reduce any additional gMG medications if you and the study doctor decide to do so. Procedures and tests during this period are similar to those done in the Screening and Double-Blind periods. Each study visit will last about 4-5 hours, not including waiting time.

Everyone will have the opportunity to take satralizumab in the Open-Label period

What happens during the Safety Follow-Up period?

The **Safety Follow-Up** period is completed after the final dose of study treatment to monitor your health and well-being.

You will enter the **Safety Follow-Up** period if:

- You stop taking the study treatment before the end of the Double-Blind period
- You complete the Double-Blind period, but you do not wish to continue in the Open-Label period
- You stop taking satralizumab before the end of the Open-Label period

The procedures and tests during these visits are similar to those done in the other study periods.

Safety Follow-Up will take up to 3 months for adults with 1 study visit and up to 6 months for teenagers with 2 visits

What are my responsibilities if I am the participant?

If you meet all the requirements to take part in the LUMINESCE study and sign the ICF/IAF, you will need to follow certain 'dos' and 'don'ts':

DO:	DO NOT:
☑ Attend study visits and complete all study procedures and tests	☒ Use certain medications that the study doctor has advised you not to take
☑ Tell your other doctors that you are taking part in this study	☒ Take part in other clinical studies while you are participating in the LUMINESCE study
☑ Always carry your Patient Identification (ID) card to inform others that you are taking part in this study, as needed	☒ Take certain vaccinations (check with the study doctor before receiving any vaccinations, including COVID-19 vaccines, during the study)
☑ Record time and dose of last cholinesterase inhibitor (e.g., pyridostigmine or neostigmine) dose prior to study visits (as applicable)	
☑ Use a reliable form of birth control if you are a woman who can become pregnant	

You will also need to tell the study doctor if:

- You have:
  - Any side effects or any new or worsened symptoms
  - Been hospitalized
  - Been admitted to the emergency room
  - Had or are planning any medical procedures
- There are any changes to your medication (including prescription, over-the-counter and herbal medication)
- There are any changes in your contact information
- You no longer want to take part in the LUMINESCE study or would like to stop treatment
- You believe you may be pregnant (if applicable)

Are there any benefits to participating in this study?

There is no guarantee that you will receive any benefits by participating in this study. Taking part in this study may or may not cause your health to improve. You will receive close medical attention from the study team throughout your involvement.

The information collected in the LUMINESCE study will help doctors learn more about satralizumab and gMG. This information may benefit you and other people with gMG to find a new treatment and improve the health of people with gMG in the future.

What are the risks associated with participating in this study?

You may have side effects from the study treatment or tests used in this study. Side effects can be mild to severe and they can vary from person to person. Your health condition will be closely monitored by the study team over the course of the study and any side effects will be cared for as appropriate.

Below is a list of side effects related to satralizumab when taken by patients with NMOSD. There may be side effects that are not known at this time.

VERY COMMON SIDE EFFECTS

(occurs in more than 10% of patients)

- Headache
- Reactions following the injection of the study treatment. These reactions can be:
  - Local to the place on the body where the injection is given (e.g., swelling, rash, redness, itching or pain)
  - General or systemic (e.g., diarrhea or headache)
- Joint pain
- Decreased white blood cell count

COMMON SIDE EFFECTS

(occurs in 1–10% of patients)

- Muscle and joint stiffness
- Rash
- Itching
- Difficulty sleeping or falling asleep
- Migraine
- Swelling of the hands, feet, or lower leg
- Hay fever
- Decreased level of a blood protein, fibrinogen, needed for blood clotting
- Increased blood level of a liver pigment called bilirubin (often a sign of liver problems)

For additional information on the risks of this study, please speak with the study doctor.

You will be closely monitored for potential risks by the study team. Your health and well-being will be the priority of the study doctor and study team

Is there any cost associated with taking part in this study?

You will not be charged for the study treatment you receive while you are taking part in this study. Additionally, any procedures that are necessary for taking part in the LUMINESCE study will be provided to you at no charge.

You will be reimbursed for any reasonable travel expenses, such as parking, taxi, bus or train fares incurred as a result of taking part in this study. Reimbursement can vary from region to region, so please check with the study doctor.

If you are injured because of taking part in this study, you will be entitled to receive compensation in accordance with national legislation. The study doctor will discuss your options and where you can receive treatment.

Do I have to take part in the LUMINESCE study? What are my options if I don't participate?

Your participation in this study is completely optional. If you are not eligible for this study or decide not to participate, you can:

- Get treatment for your gMG without being in this study
- Participate in a different clinical study for gMG
- Choose to receive no gMG treatment

Please talk to your doctor about other options that may be right for you and your family. It is important that you take the time to carefully consider this clinical study as an option for you.

Important reminders and contact information

The LUMINESCE study will follow strict rules to help protect your safety and rights.

Your health and well-being will be the priority of the study doctor and the study team

Taking part in a clinical study is entirely your choice. The decision for you to take part or not should only be made after the study doctor has:

- Provided you with all necessary information regarding the study
- Explained what taking part in the study would involve
- Answered any of your questions about the study

Please remember you may choose to stop participating in the study at any time for any reason. Leaving the study will not affect your usual healthcare. Be sure to speak with the study doctor before making any decisions

I am interested. What do I do next?

The LUMINESCE team is currently looking for individuals to join this clinical study. If you or someone you know may qualify for this study and is interested in learning more, please contact the study team:

Contact name:

Study center name:

Study center address:

Telephone:

Email:

Questions/notes to discuss with the study doctor

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WE ARE FOCUSED ON THE SEARCH FOR A BRIGHTER gMG FUTURE

LUMINESCE