MEDICATION GUIDE

LYFGENIA® (pronounced lif-*JEN-ee-uh*)

(lovotibeglogene autotemcel)

What is the most important information I should know about LYFGENIA?

Patients treated with LYFGENIA have developed blood cancers. Treatment with LYFGENIA may increase your risk of developing blood cancer. Blood cancer can develop many years after treatment with LYFGENIA. Blood cancer can be life-threatening and/or cause death.

Because of the risk of blood cancer, you should talk to your doctor about the benefits and risks of LYFGENIA, and about your treatment options. Your doctor may evaluate if you have risk factors that increase your chances of developing blood cancer after LYFGENIA.

Because of the risk of cancer, it is important for you to be monitored at least every 6 months for a minimum of 15 years after LYFGENIA. Monitoring will include blood tests that measure your blood cell counts and evaluation of the blood cells where the gene product is present with specialized tests. If these tests are abnormal, additional testing may be recommended by your doctor. Additional testing might include more frequent blood tests to watch you more closely for changes in your blood. Additional testing could also include a bone marrow evaluation, which can tell your doctor if a blood cancer is developing.

Blood cancer may cause no symptoms, or symptoms can be general. You or your caregiver should call your healthcare provider right away for any of these signs or symptoms:

- Abnormal bruising or bleeding (including nosebleed)
- Blood in urine, stool, or vomit
- Coughing up blood
- Severe headache
- Unusual stomach or back pain
- Fever (100.4°F/38°C or higher)
- Swollen glands
- Abnormal tiredness

If you are diagnosed with a cancer, have your treating physician contact Genetix Biotherapeutics at 1-833-999-6378.

You may experience side effects associated with other medicines administered as part of the LYFGENIA treatment regimen. Talk to your physician regarding those possible side effects. Your healthcare providers may give you other medicines to treat your side effects.

It is important that you or your caregiver tell your healthcare providers that you have received LYFGENIA.

What is LYFGENIA?

LYFGENIA is a one-time gene therapy to treat sickle cell disease. Sickle cell disease is a genetic, inherited, lifelong disease caused by an alteration in one of the genes in the red blood cell, the beta-globin gene, that causes the normal disc-shaped red cells to take the

shape of a sickle, causing anemia and vaso-occlusive events, like a pain crisis. LYFGENIA is made specifically for each patient, using the patient's own blood stem cells (from which red blood cells are produced). It adds functional copies of the beta-globin gene to your cells leading to production of anti-sickling hemoglobin that may decrease or stop vaso-occlusive events.

How will I get LYFGENIA?

Before treatment: Your healthcare providers will give you other medicines, including a chemotherapy medicine (given in the vein), as part of your treatment with LYFGENIA. It's important to talk to your healthcare provider about the risks and benefits of all medicines involved in your treatment. You will be admitted to a treatment center during this process (see Step 3).

After receiving the chemotherapy, it may not be possible for you to become pregnant or father a child. You should consider discussing options for fertility preservation with your doctor before treatment.

STEP 1: LYFGENIA is made specifically for you from your own blood stem cells. Your healthcare provider will collect your blood stem cells through a procedure/process called mobilization and apheresis *(A-feh-REE-sis)*. This process takes approximately one week and may need to be repeated to obtain a sufficient number of cells.

'Back-up' stem cells (or 'rescue cells') are also collected and stored at the treatment center. This is a precaution in case there is a problem in the treatment process. If this happens, your back-up stem cells will be given back to you. If you receive back-up cells, you will have no benefit from LYFGENIA.

STEP 2: Your blood stem cells will be sent to a manufacturing site where they are used to make your LYFGENIA. It typically takes 10 to 15 weeks from the time your cells are collected to make and test LYFGENIA before it is shipped to your healthcare provider, but the time may vary.

STEP 3: Before you receive LYFGENIA, your healthcare provider will give you chemotherapy for a few days to make room in the bone marrow. You will be admitted to the treatment center for this step and remain there until after LYFGENIA infusion.

STEP 4: LYFGENIA is given by an intravenous infusion (into your vein). You may receive more than one bag of LYFGENIA. Each bag is infused in 30 minutes or less.

After LYFGENIA infusion, you will stay in the treatment center for approximately 3-6 weeks so that your healthcare team can closely monitor your recovery. Your healthcare provider will determine when you can go home.

What should I avoid after receiving LYFGENIA?

- Do not donate blood, organs, tissues or cells.

What are the possible side effects of LYFGENIA?

The possible side effects of LYFGENIA include:

- On the day of treatment with LYFGENIA
  - Low blood pressure
  - Hot flush

- Following treatment
    - **Blood cancer.** Refer to "What is the most important information I should know about LYFGENIA?"
    - Longer time for platelets to recover, which may reduce the ability of blood to clot and may cause bleeding

These are not all the possible side effects of LYFGENIA. Call your doctor for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088 or to Genetix Biotherapeutics at 1-833-999-6378.

General information about the safe and effective use of LYFGENIA.

It is important that you have regular check-ups with your healthcare provider, including blood tests at least every 6 months as advised by your health-care provider, to detect any adverse effects and to confirm that LYFGENIA is still working.

Patients treated with LYFGENIA are encouraged to enroll in a post-marketing study to assess the long-term safety of LYFGENIA and the risk of blood cancers occurring after treatment with LYFGENIA. Patients should discuss the option to participate with their physician.

LYFGENIA will not give you a human immunodeficiency virus (HIV) infection. Treatment with LYFGENIA may cause a false-positive HIV test result by some commercial tests (specifically, a PCR-based test). If you need to have an HIV test, talk with your healthcare provider about the appropriate test to use.

Talk to your healthcare provider about any concerns. You can ask your healthcare provider for information about LYFGENIA that is written for healthcare professionals.

For more information, go to LYFGENIA.com or call 1-833-666-2583 for Patient Services.

Manufactured for: **Genetix Biotherapeutics Inc., Somerville, Massachusetts 02145**

This Medication Guide has been approved by the U.S. Food and Drug Administration.
Issued: December 2023
LYF-US-00060-v2 2/26