LYFGENIA™ is *the longest-studied* approved gene therapy* for sickle cell disease.

*The clinical study for LYFGENIA started in February 2015.

What is LYFGENIA?

LYFGENIA is a one-time gene therapy to treat sickle cell disease in patients 12 years of age or older and a history of vaso-occlusive events. 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.

Important Safety Information

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

At the time of initial FDA approval, three patients were diagnosed with blood cancer. Two patients were treated with an earlier version of LYFGENIA using a different manufacturing process and transplant procedure and one patient had α-thalassemia trait.

Please see Important Safety Information on pages 14-15 and full Prescribing Information, including Boxed WARNING and Medication Guide for LYFGENIA.

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suspension for IV infusion

Learn about LYFGENIA, a *gene therapy option*

Managing sickle cell disease (SCD) can be challenging and can affect different aspects of your life. What if you had the power to treat SCD from within, without a donor?

LYFGENIA is a **one-time** treatment for sickle cell disease. It helps your body make working adult hemoglobin that does not sickle. The working adult hemoglobin helps to reduce or stop sickle cell crises, also known as vaso-occlusive events (VOEs).*

LYFGENIA is for individuals 12 years or older with a history of sickle cell crises (VOEs).

*See page 11 for the definition of VOEs.

This resource is for education only. It does not replace medical advice, diagnosis, or treatment. Talk to your healthcare team about any questions you may have.

Important Safety Information (cont'd)

What is the most important safety information I should know about LYFGENIA? (cont'd)

Treatment with LYFGENIA may increase your risk of developing blood cancer, which can be life-threatening and/or cause death and can develop many years after treatment with LYFGENIA. Because of this risk, 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, which might include more frequent blood tests and a bone marrow evaluation.

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.

Please see Important Safety Information on pages 14-15 and full Prescribing Information, including Boxed WARNING and Medication Guide for LYFGENIA.

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Words that are underlined indicate terms you can find in the Glossary on pages 26-27.

LYFGENIA is specifically made for you using *your own cells*

Please see Important Safety Information on pages 14-15 and full Prescribing Information, including Boxed WARNING and Medication Guide for LYFGENIA.

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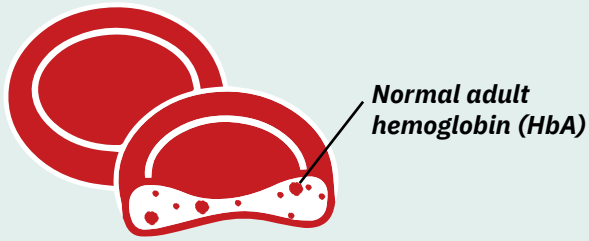
Sickle cell disease (SCD) *explained*

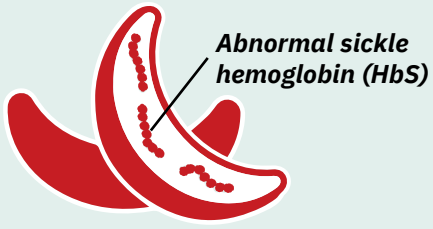
SCD begins in your genes, but it doesn't stop there.

Knowing the root cause of SCD—a gene mutation that produces abnormal hemoglobin—is an important first step in making decisions with your doctor on how to treat it.

Over time, sickled red blood cells can block and damage blood vessels, keeping oxygen from reaching your organs and tissues. This can cause severe pain from a sickle cell crisis (VOE). A sickle cell crisis can happen without warning and may require hospital care.



Normal red blood cell



Sickled red blood cell

A change in one of the genes that help make blood stops your body from making normal adult hemoglobin (HbA)

Instead, it makes a different kind of hemoglobin (HbS) that can cause your red blood cells to change shape, or "sickle"

When your red blood cells sickle, they can stick together and block tiny blood vessels, leading to painful sickle cell crises (VOEs)

 Words that are underlined indicate terms you can find in the Glossary on pages 26-27.

Current disease-modifying therapies manage symptoms but don't address the root cause

Today, most people with SCD rely on treatments that help with symptoms caused by SCD.

Disease-modifying therapies (DMTs), pain medicines (taken by mouth or through IV), and blood transfusions are used to help manage sudden and severe symptoms, like pain. These treatments are usually taken for their entire life.

Other treatment options exist, such as allogeneic stem cell transplants (also known as bone marrow transplants).

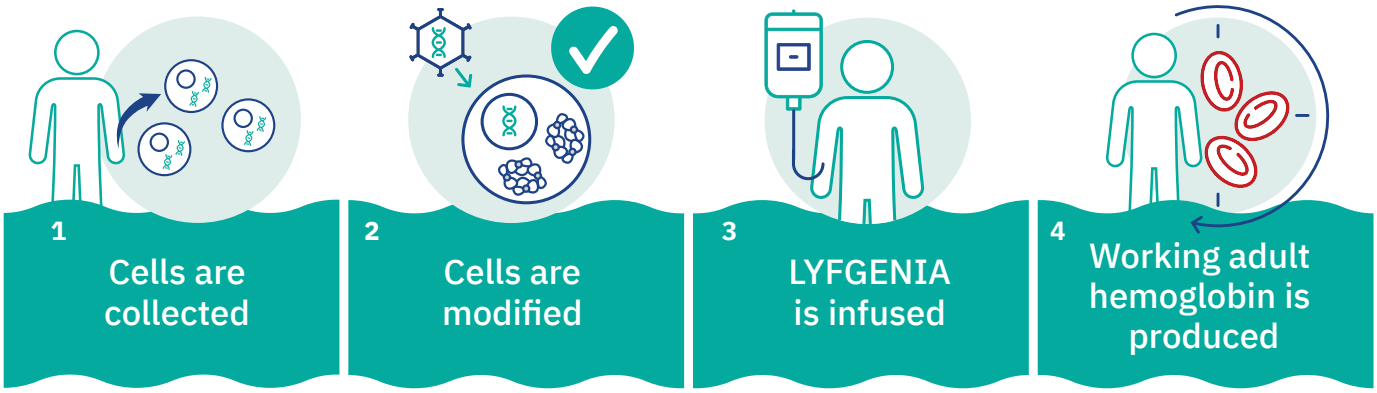
This one-time treatment requires a matched donor and is recommended for patients under the age of 16. Because the cells come from another person, they may cause more harm by attacking the body.
This is called graft-versus-host disease.

A treatment that addresses the root cause may finally offer a *different path forward*

 Words that are underlined indicate terms you can find in the Glossary on pages 26-27.

How LYFGENIA works to address the *root cause* of sickle cell disease

LYFGENIA is a gene addition therapy—adding a gene to your own cells so you can create modified, working adult hemoglobin that doesn't sickle, without the need of a donor.



1. Your blood stem cells are collected.
2. Your collected cells are modified to add a gene to make working adult hemoglobin that doesn't sickle.
3. Your new cells (LYFGENIA) are returned to your body through an IV infusion.
4. This leads to your body creating its own new red blood cells with working adult hemoglobin that does not sickle.

Important Safety Information (cont'd)

What is the most important safety information I should know about LYFGENIA? (cont'd)

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

Please see Important Safety Information on pages 14-15 and full Prescribing Information, including Boxed WARNING and Medication Guide for LYFGENIA.

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Words that are underlined indicate terms you can find in the Glossary on pages 26-27.

LYFGENIA helps your body produce working *adult hemoglobin that does not sickle* to potentially reduce or stop painful sickle cell crises (VOEs)

Please see Important Safety Information on pages 14-15 and full Prescribing Information, including Boxed WARNING and Medication Guide for LYFGENIA.

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LYFGENIA is the longest-studied* *approved* gene therapy for sickle cell disease

This study design explains important information about the clinical trial for LYFGENIA.

45 people
were treated with LYFGENIA in the clinical trial and followed to evaluate the safety profile of the treatment

The median age was
25 years
(patient ages ranged from 12 to 43)

Median† duration of follow-up for individuals evaluated for safety:
42 months
(minimum of 12 months, maximum of 87 months)

*The primary clinical trial that evaluated LYFGENIA started in February 2015.

†The median is the middle number in a list of numbers arranged from smallest to largest.

Important Safety Information (cont'd)

What is the most important safety information I should know about LYFGENIA? (cont'd)

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, including a chemotherapy medicine, administered as part of the LYFGENIA treatment regimen. 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.

Please see Important Safety Information on pages 14-15 and full Prescribing Information, including Boxed WARNING and Medication Guide for LYFGENIA.

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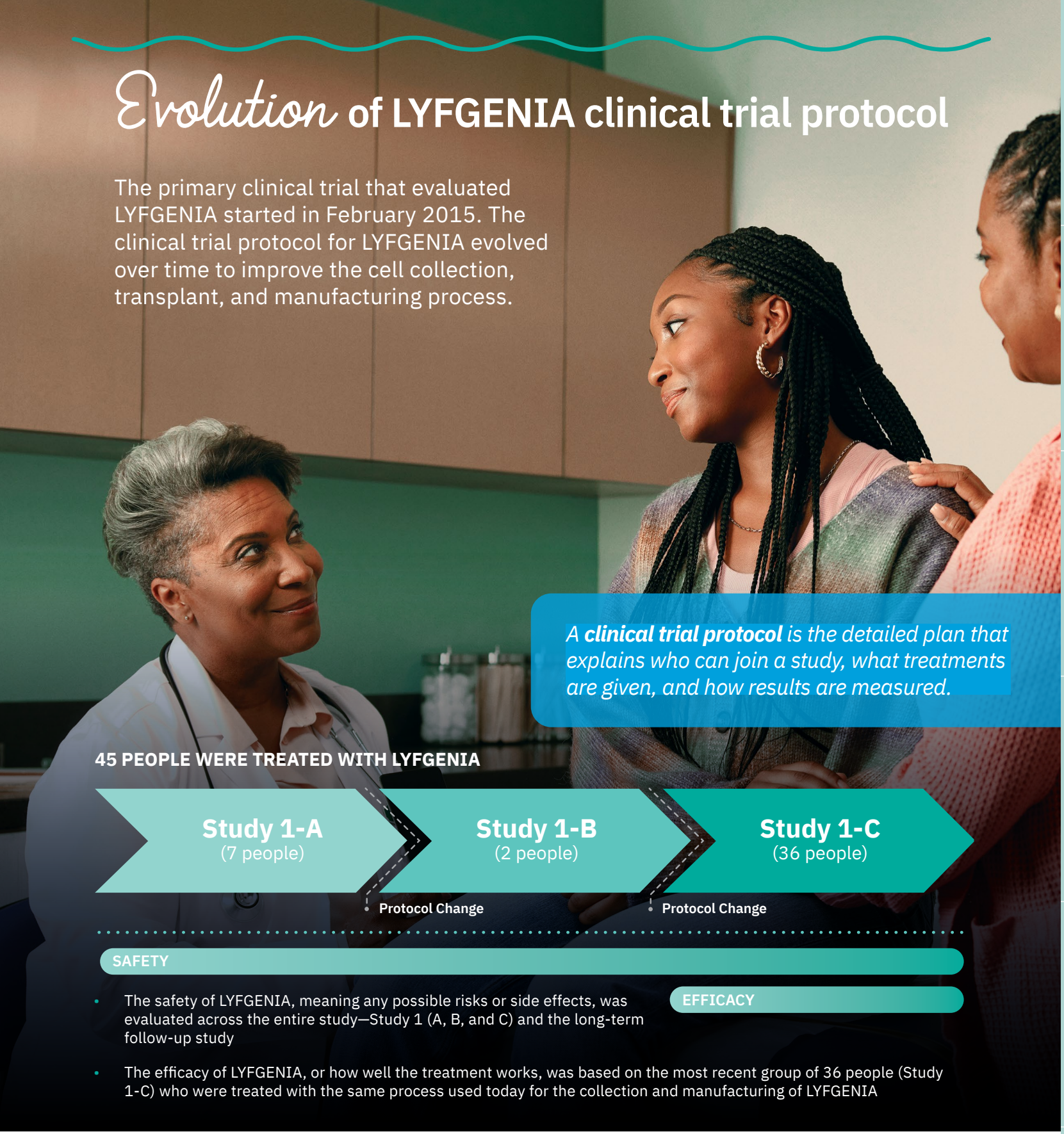
Evolution of LYFGENIA clinical trial protocol

The primary clinical trial that evaluated LYFGENIA started in February 2015. The clinical trial protocol for LYFGENIA evolved over time to improve the cell collection, transplant, and manufacturing process.



*A **clinical trial protocol** is the detailed plan that explains who can join a study, what treatments are given, and how results are measured.*

45 PEOPLE WERE TREATED WITH LYFGENIA

Study 1-A
(7 people)

Study 1-B
(2 people)

Study 1-C
(36 people)

Protocol Change

Protocol Change

SAFETY

- The safety of LYFGENIA, meaning any possible risks or side effects, was evaluated across the entire study—Study 1 (A, B, and C) and the long-term follow-up study

EFFICACY

- The efficacy of LYFGENIA, or how well the treatment works, was based on the most recent group of 36 people (Study 1-C) who were treated with the same process used today for the collection and manufacturing of LYFGENIA

Please see Important Safety Information on pages 14-15 and full Prescribing Information, including Boxed WARNING and Medication Guide for LYFGENIA.

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A *one-time* transformational therapy with the potential to decrease or stop sickle cell crises (VOEs)

The efficacy of LYFGENIA was studied in 36 individuals; 32 of the participants had at least 4 sickle cell crises (VOEs) in the 2 years before the clinical trial.

After receiving LYFGENIA, these 32 individuals were monitored to see how many sickle cell crises they experienced between **6-18 months after treatment**.

did not experience any VOEs
(28/32 people)

did not experience any severe vaso-occlusive events (sVOEs)
(30/32 people)

- Four individuals who did not experience any VOEs between 6-18 months after treatment later experienced VOEs
- The treatment worked similarly and had a similar safety profile in adults and adolescents
- The median duration of follow-up for efficacy for the 36 individuals who received LYFGENIA was 38 months (minimum of 12 months, maximum of 61 months)

*LYFGENIA is the **only approved SCD gene therapy** where patients were assessed for sickle cell crises (VOEs) during the same set time frame, from 6 to 18 months after treatment, to ensure patients were evaluated using the same set time frame.*

Important Safety Information (cont'd)

What is the most important safety information I should know about LYFGENIA? (cont'd)

Talk to your healthcare provider about the risks and benefits of all medicines involved in your treatment.

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

Please see Important Safety Information on pages 14-15 and full Prescribing Information, including Boxed WARNING and Medication Guide for LYFGENIA.

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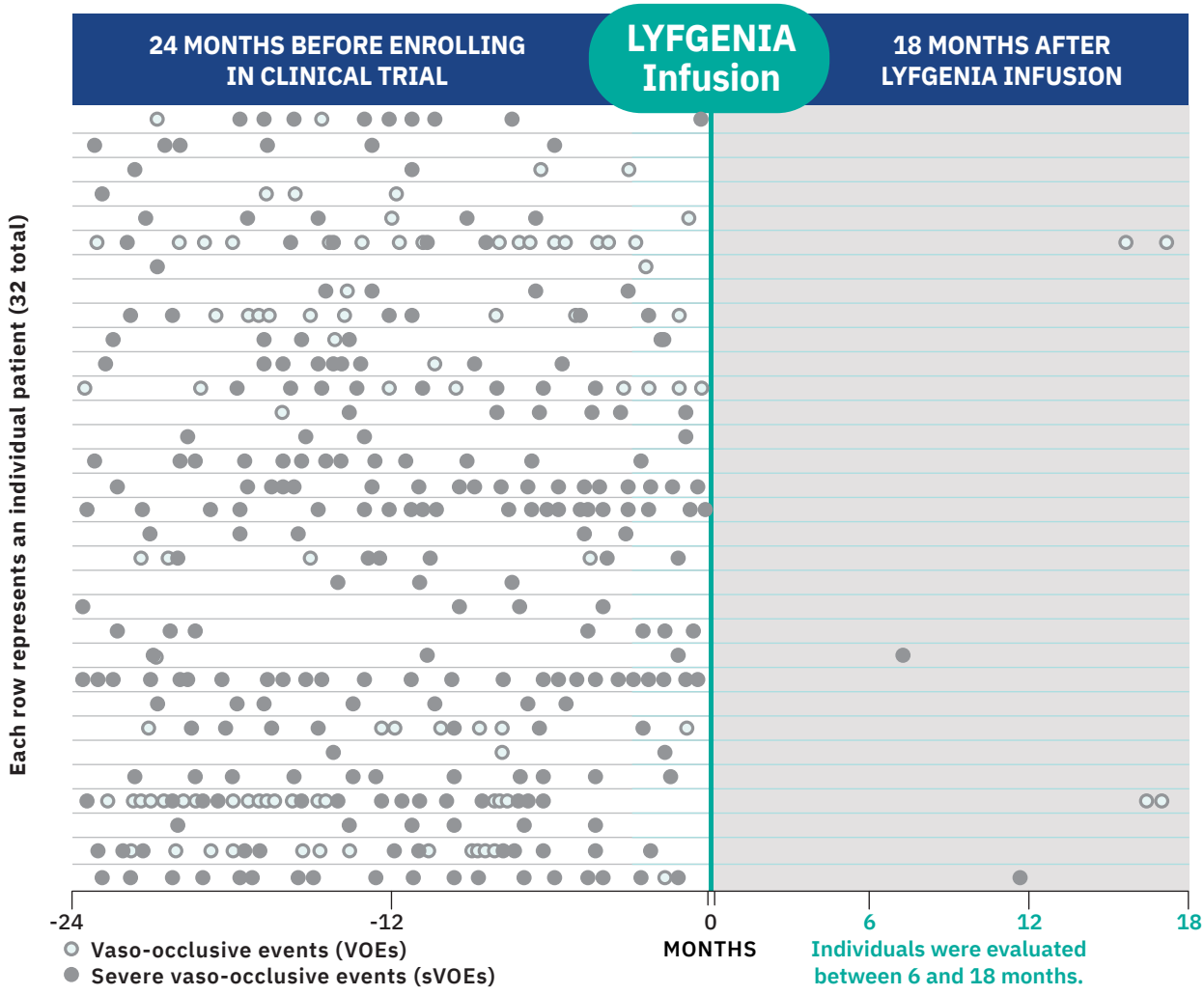
VASO-OCCLUSIVE EVENTS (VOEs) BEFORE AND AFTER LYFGENIA INFUSION



sVOEs were also counted as VOEs.

This figure is not included in the LYFGENIA Prescribing Information.

- **Vaso-occlusive events (VOEs)** were defined as any of the following events requiring evaluation at a medical facility: an episode of acute pain with no medically determined cause other than vaso-occlusion lasting more than 2 hours, acute chest syndrome, acute hepatic sequestration, or acute splenic sequestration
- **Severe vaso-occlusive events (sVOEs)** were defined as either of the following events: VOEs requiring a hospitalization or multiple visits to an emergency department/urgent care over 72 hours and receiving IV medications at each visit, or priapism requiring any level of medical attention

Important Safety Information (cont'd)

What should I avoid after receiving LYFGENIA?

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

Please see Important Safety Information on pages 14-15 and full Prescribing Information, including Boxed WARNING and Medication Guide for LYFGENIA.

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Long-term findings after LYFGENIA treatment

Results for people with a history of stroke

Five adults 18 years and older who had a history of stroke or blood vessel problems were receiving chronic red blood cell transfusions before LYFGENIA.

All 5 no longer needed red blood cell transfusions and have remained stroke-free for ~4–5 years (44–60 months) after treatment.

What patients reported about their pain and fatigue after LYFGENIA

In an analysis of 20 people, more than half reported that their pain, pain interference, and tiredness improved at 3 years after treatment.

*Pain interference is the impact of pain on your ability to perform everyday tasks.

Important Safety Information (cont'd)

What are the possible side effects of LYFGENIA?

The possible side effects of LYFGENIA on the day of treatment include: Low blood pressure and hot flush.

The possible side effects of LYFGENIA following treatment include: **Blood cancer** and longer time for platelets to recover, which may reduce the ability of blood to clot and may cause bleeding.

Please see Important Safety Information on pages 14-15 and full Prescribing Information, including Boxed WARNING and Medication Guide for LYFGENIA.

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Eligibility is not one-size-fits-all

A wide range of people may be eligible for gene therapy with LYFGENIA

Talk to your doctor about LYFGENIA if you:

- Have sickle cell disease and a history of sickle cell crises (VOEs) and are at least 12 years old; **there's no upper age limit for treatment with LYFGENIA**
- Have ongoing crises from sickle cell disease and **want to reduce the burden**
- Are looking for a way to take control of your future, **by potentially reducing or eliminating sickle cell crises (VOEs)**
- Have a history of stroke, and **worry about having another one**
- Want to learn how gene therapy and the treatment process could impact **school, career, or family**
- Want to learn whether **gene therapy could still be an option**, even if you've already experienced organ damage or other complications

Remember: *You don't have to fit a certain profile to ask about gene therapy. If you're interested in learning more about LYFGENIA, enrolling in Patient Support Services can get you started by connecting you with a Qualified Treatment Center.*

Visit **GenetixPatientSupport.com** or call **1-833-888-6378**

Important Safety Information (cont'd)

What are the possible side effects of LYFGENIA? (cont'd)

These are not all the possible side effects of LYFGENIA. Call your doctor for medical advice about side effects. You are encouraged to report side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

Please see Important Safety Information on pages 14-15 and full Prescribing Information, including Boxed WARNING and Medication Guide for LYFGENIA.

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Important Safety Information

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

At the time of initial FDA approval, three patients were diagnosed with blood cancer. Two patients were treated with an earlier version of LYFGENIA using a different manufacturing process and transplant procedure and one patient had α-thalassemia trait.

Treatment with LYFGENIA may increase your risk of developing blood cancer, which can be life-threatening and/or cause death and can develop many years after treatment with LYFGENIA. Because of this risk, 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, which might include more frequent blood tests and a bone marrow evaluation.

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. 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, including a chemotherapy medicine, administered as part of the LYFGENIA treatment regimen. 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. Talk to your healthcare provider about the risks and benefits of all medicines involved in your treatment. It is important that you or your caregiver tell your healthcare providers that you have received LYFGENIA.

How will I get LYFGENIA?

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. 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.

Please see full Prescribing Information, including Boxed WARNING and Medication Guide for LYFGENIA.

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Important Safety Information (cont'd)

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 and be up to 22 weeks.

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. 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 on the day of treatment include: Low blood pressure and hot flush.

The possible side effects of LYFGENIA following treatment include: **Blood cancer** and 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 are encouraged to report side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

General Information

It is important that you have regular check-ups with your healthcare provider to detect any adverse effects and to confirm that LYFGENIA is still working. Talk to your healthcare provider about any concerns.

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 uses a vector that is based on the blueprint of the human immunodeficiency virus (HIV) to deliver genetic material to your cells. LYFGENIA will not give you a 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.

Please see full Prescribing Information, including Boxed WARNING and Medication Guide for LYFGENIA.

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LYFGENIA—a *path* to consider taking

Where will you receive LYFGENIA?

Before treatment, individuals and their healthcare providers will work together to consider whether LYFGENIA is right for them.

People who are prescribed LYFGENIA will receive treatment as a one-time infusion at a Qualified Treatment Center (QTC). Each QTC has been carefully selected based on its expertise in areas such as transplants or cell and gene therapy.

It's important to consult with your regular physicians as well as specialists in gene therapy.

We want you to have the support you need.

When you enroll in Genetix Patient Support Program, a Patient Navigator can provide dedicated support and help answer your questions about the treatment process, navigating insurance, identifying QTC options, and more.

Visit **GenetixPatientSupport.com** and pages 22-23 for more information.

Please see Important Safety Information on pages 14-15 and full Prescribing Information, including Boxed WARNING and Medication Guide for LYFGENIA.

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A process focused on *you*

Please see Important Safety Information on pages 14-15 and full Prescribing Information, including Boxed WARNING and Medication Guide for LYFGENIA.

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One-time *treatment process*

Treatment with LYFGENIA involves coordinating with a care team and confirming that gene therapy is an appropriate choice for you and your family.

Planning plays a large role in deciding if gene therapy is right for you, from healthcare coverage and impacts on daily life (including work and family responsibilities) to chemotherapy and fertility discussions.

6 key steps

It's important to keep in mind that the time frames are estimates. Your journey may look different depending on your circumstances, unique to you and your care team at the QTC.

Step 1:
Pre-treatment

Step 2*:
Stem Cell Collection

Step 3:
LYFGENIA Creation

Step 4:
Conditioning Chemotherapy

Step 5:
LYFGENIA Infusion

Step 6:
Recovery and
Long-term Follow-up

Additional safety considerations

LYFGENIA is made from patients' own cells; therefore, there have been no cases of graft failure or graft rejection. Please see **full Prescribing Information**, which includes Warnings for Delayed Platelet Engraftment and Neutrophil Engraftment Failure.

*This step may need to be repeated.

Please see Important Safety Information on pages 14-15 and full Prescribing Information, including Boxed WARNING and Medication Guide for LYFGENIA.

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One-time *treatment process* (cont'd)

AT THE QTC

Step 1:

Pre-treatment

(Outpatient)

Prepare for your treatment process

- Before stem cell collection, you'll work with your care team to understand all the medicines you may have to start or stop as part of the LYFGENIA treatment process
- To prepare your body, you'll need at least 2 cycles of red blood cell transfusions; this is to help keep hemoglobin levels high enough for stem cell collection

AT THE QTC

Step 2:

Stem Cell Collection

(~1 week at a QTC)

Your blood stem cells are collected

- Your doctor will collect your blood stem cells using mobilization and apheresis
  - Mobilization moves stem cells from your bone marrow into your bloodstream
  - Apheresis filters those cells out of your blood
- "Back-up" stem cells (also called rescue cells) are collected and saved at the treatment center in case they are needed later
  - If back-up cells are used, you will not receive LYFGENIA
- Most people provide enough stem cells with 1–2 cycles, but sometimes more may be needed

One-time *treatment process* (cont'd)

AT HOME

AT THE QTC

Step 3:

LYFGENIA Creation

(10–15 weeks)

Your cells are sent away to create your LYFGENIA

- Your stem cells are shipped to a manufacturing site
- There, your personal LYFGENIA treatment is created and tested
- This part of the process can take as little as 70 days

Step 4:

Conditioning Chemotherapy

(4 days plus ≥2 days of recovery at a QTC)

Making room for the new cells

- You'll be admitted to the treatment center for 4 days of chemotherapy and a couple of days for recovery
- This helps your body make space for your new cells
- After chemotherapy, fertility may be affected
  - Genetix Patient Support Program can discuss options for fertility support

You may be encouraged to take part in the LYFGENIA registry by calling Genetix Biotherapeutics at **1-833-999-6378**. By joining, you can help researchers better understand the long-term safety and effectiveness of treatment for up to 15 years. Participation is completely voluntary.

Important Safety Information (cont'd)

General Information

LYFGENIA uses a vector that is based on the blueprint of the human immunodeficiency virus (HIV) to deliver genetic material to your cells. LYFGENIA will not give you a 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.

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One-time *treatment process* (cont'd)

AT THE QTC

Step 5:

LYFGENIA Infusion

(~30 minutes per bag at a QTC)

You receive your modified LYFGENIA cells

- LYFGENIA is given through an IV, like a blood transfusion
- You may receive 1–4 bags; the number varies by person

AT THE QTC

Step 6:

Recovery and Long-term Follow-up

(~3–6 weeks of monitoring at a QTC followed by long-term follow-up for at least 15 years)

Monitoring your recovery before going home

- You'll stay at the treatment center for 3–6 weeks so the team can oversee your recovery. They will monitor you for safety and for engraftment—the process by which the transplanted cells make new blood cells and platelets in your body—to make sure your cell counts are high enough
- After you leave, you'll continue regular follow-up, including blood tests, with your healthcare professional for at least 15 years. The QTC may require you to return for follow-up care at their center
- These check-ins help your doctor make sure LYFGENIA is working and detect any side effects
- 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. If these tests are abnormal, additional testing may be recommended, which can include more frequent blood tests and a bone marrow evaluation. If you are diagnosed with a cancer, have your treating physician contact Genetix Biotherapeutics at 1-833-999-6378

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Support that never stops

Enroll today

to begin your LYFGENIA journey with unparalleled support at every step.

From the moment you decide you want to explore treatment with LYFGENIA, the Genetix Patient Support Program is available to you, even before you talk to your doctor or get a prescription.

Genetix Patient Support Program guides you and your loved ones through the treatment journey while connecting you with helpful people and organizations.

A Patient Navigator is available at no cost to answer questions, share resources, and help you with taking that next step.

No prescription needed; you can connect with a QTC at any time.

Genetix is committed to supporting our patients every step of the way to ensure the best experience possible. We are working constantly to expand access, improve the LYFGENIA process, and partner with the sickle cell community throughout their journey.

Please see Important Safety Information on pages 14-15 and full Prescribing Information, including Boxed WARNING and Medication Guide for LYFGENIA.

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Once enrolled, you will be connected with a dedicated Patient Navigator *at no cost*, who can:

- Offer ongoing help before, during, and after treatment
- Connect you with a QTC and assist with travel and lodging*
- Guide you through insurance and financial assistance options*
- Provide resources and support for fertility preservation*
- Offer peer-to-peer support by linking you to others who've experienced treatment firsthand

*Eligibility requirements and restrictions apply. Patient must be enrolled in Patient Support Services to determine eligibility for, and participate in, program offerings.

For additional support and to connect with a Patient Navigator:

Call 1-833-888-6378
Email patientsupport@genetixbiotx.com
Visit GenetixPatientSupport.com

Having a single point of contact means you'll never have to manage the process alone. **Enroll today!**

Genetix Patient Support Program: Dedicated support for *your journey* with LYFGENIA

Please see Important Safety Information on pages 14-15 and full Prescribing Information, including Boxed WARNING and Medication Guide for LYFGENIA.

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Questions for your doctor

Deciding to move forward with LYFGENIA is a big decision. Before discussing LYFGENIA with your doctor (or your loved one's doctor), consider the following questions to help you get started.

Thinking about LYFGENIA

Am I a candidate for LYFGENIA?

How do you think LYFGENIA could change my experience with sickle cell disease?

What safety considerations should I know about LYFGENIA?

What are the possible side effects of LYFGENIA?

What should I do if I'm planning to have kids?

Moving forward with LYFGENIA treatment

Where will I go to receive LYFGENIA?

Who will oversee my treatment?

What can I expect at the QTC?

Where will I be monitored after LYFGENIA and for how long?

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Questions for your QTC care team

The following questions can help you get a better understanding of the treatment process in general during consultations with your healthcare team.

Is there anything I should avoid after treatment with LYFGENIA?

Who will monitor my follow-up?

What are the most important things to know about receiving treatment at a QTC?

What will I need to consider and plan for in order to move forward with LYFGENIA (eg, transportation, cost, or community and family support)? What logistics will I need to address beforehand?

What do I need to know about what happens after treatment with LYFGENIA? What does follow-up care look like?

What should I do if I experience any sickle cell disease-related symptoms during or after treatment?

What should I do if I experience side effects during or after treatment?

What else should I know about LYFGENIA before I start planning for treatment?

Important terms you should know

Reference this page to revisit any new or unfamiliar terms in this brochure to help your understanding as you manage sickle cell disease care.

Allogeneic stem cell transplant: replacing a person's unhealthy blood-forming stem cells with those of a well-matched healthy donor; also called a hematopoietic stem cell transplant (HSCT) or bone marrow transplant (BMT)

Apheresis: part of the stem cell collection process that involves separating stem cells from the blood using a machine, then returning the remaining blood to the body

Blood stem cell: an immature cell that has the potential to develop into any blood cell type, including white blood cells, red blood cells, and platelets

Conditioning: a process that clears space in the bone marrow so new stem cells from gene therapy or a stem cell transplant can grow; this is usually done using chemotherapy, radiotherapy, and/or immunotherapy and is required for all transplant options

Engraftment: the process by which transplanted stem cells travel through the blood to the bone marrow, where they begin to make new white blood cells, red blood cells, and platelets

Gene: a part of your DNA responsible for controlling inherited traits

Gene addition therapy: a treatment that uses a viral vector to add new genes into cells, giving them new instructions to help change the course of the disease

Graft-versus-host disease: a reaction where the donated stem cells attack the host's body due to viewing it as foreign

Hemoglobin: a protein in red blood cells that carries oxygen throughout your body

Infusion: a continuous, slow administration of a treatment into your veins

Median: the middle number in a list of numbers arranged from smallest to largest

Important terms you should know (cont'd)

Mobilization: the first part of the stem cell collection process that moves stem cells out of the bone marrow and into the circulating blood

Mutation: an abnormal change in a gene that causes it to malfunction

Genetix Patient Support Program: a program to help guide you through each step of the LYFGENIA treatment journey

Patient Navigator: a patient support specialist at the **Genetix Patient Support Program** who is knowledgeable about LYFGENIA and is equipped with resources to help navigate questions, including concerns about healthcare insurance or treatment planning

Proteins: the molecules within cells that are responsible for performing important functions, such as delivering oxygen throughout the body

Qualified Treatment Center (QTC): a hospital that has been carefully selected based on expertise in areas such as transplants or cell and gene therapy, with staff trained to administer LYFGENIA

Red blood cell: a hemoglobin-containing cell that carries oxygen throughout your body

Severe vaso-occlusive events (sVOEs): Vaso-occlusive events (VOEs) requiring a hospitalization or multiple visits to an emergency department/urgent care over 72 hours and receiving IV medications at each visit, or priapism requiring any level of medical attention

Sickle hemoglobin: an abnormal form of the hemoglobin protein that causes red blood cells to become sickled (or half-moon shaped)

Vaso-occlusive events (VOEs): Any of the following events requiring evaluation at a medical facility: an episode of acute pain with no medically determined cause other than vaso-occlusion lasting more than 2 hours, acute chest syndrome, acute hepatic sequestration, or acute splenic sequestration

Vector: a delivery system used to introduce genetic material into the cell

Ask your doctor about LYFGENIA today.
Scan here or visit LYFGENIA.com to learn more.

What is LYFGENIA?

LYFGENIA is a one-time gene therapy to treat sickle cell disease in patients 12 years of age or older and a history of vaso-occlusive events. 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.

Important Safety Information

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

At the time of initial FDA approval, three patients were diagnosed with blood cancer. Two patients were treated with an earlier version of LYFGENIA using a different manufacturing process and transplant procedure and one patient had α-thalassemia trait.

Treatment with LYFGENIA may increase your risk of developing blood cancer, which can be life-threatening and/or cause death and can develop many years after treatment with LYFGENIA. Because of this risk, 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, which might include more frequent blood tests and a bone marrow evaluation.

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