Keeping an eye on late-onset Pompe disease

NEXVIAZYME® (avalglucosidase alfa-ngpt) is used for the treatment of patients 1 year of age and older with late-onset Pompe disease.

The answers you provide here are to help evaluate how you're doing and how to prepare for your next discussion with your healthcare provider.

How I'm feeling physically since my last checkup.

(1 is same as last visit, and 10 is noticed a lot of change.)

1 2 3 4 5 6 7 8 9 10

Things I've noticed a difference in or have difficulty doing

BREATHING

- ☐ More breathless during and/or after exercise
- ☐ Waking up throughout the night feeling breathless
- ☐ Weak cough

Breathing issues can cause other symptoms as well. I've been experiencing more:

- ☐ Morning headaches
- ☐ Daytime sleepiness

MOVING

- ☐ Harder to climb stairs
- ☐ More difficult to get up from a chair
- ☐ Using a mobility aid or device while walking
- ☐ Walking slower or with more of a waddle
- ☐ Difficulty maintaining balance while walking or standing
- ☐ More trouble reaching over my head
- ☐ More difficulty doing everyday tasks, like washing or brushing my hair
- ☐ More difficulty beginning or continuing physical exercises

OTHER

- ☐ Difficulty chewing/swallowing
- ☐ Unexplained weight loss
- ☐ Tongue weakness
- ☐ Pain

Am I feeling more fatigued than usual?

(1 is not more than usual, and 10 is feeling extreme fatigue.)

1 2 3 4 5 6 7 8 9 10

I feel my current management plan is still helping my late-onset Pompe disease.

☐ YES ☐ COULD BE BETTER ☐ NO ☐ UNSURE

IMPORTANT SAFETY INFORMATION

WARNING: SEVERE HYPERSENSITIVITY REACTIONS, INFUSION-ASSOCIATED REACTIONS, and RISK OF ACUTE CARDIORESPIRATORY FAILURE IN SUSCEPTIBLE PATIENTS

Hypersensitivity Reactions Including Anaphylaxis

If you are taking NEXVIAZYME, you should know that severe and potentially life-threatening allergic-type reactions known as anaphylaxis and severe hypersensitivity reactions have occurred during and after NEXVIAZYME treatment. You should seek immediate medical care if signs and symptoms of anaphylaxis or hypersensitivity reactions occur. If such a reaction is severe enough, your doctor may decide to immediately discontinue the infusion and provide immediate medical care. Appropriate medical support measures may be administered during your infusion, and you may require close observation during and after NEXVIAZYME administration.

Please see additional Important Safety Information continued on the following pages and full Prescribing Information, including **Boxed WARNING**.

Nexviazyme®
(avalglucosidase alfa-ngpt)

Keeping an eye on late-onset Pompe disease

Other things I'd like to discuss:

Together with your healthcare providers, you can discuss if NEXVIAZYME is a treatment option that is right for you.

NEXVIAZYME is an enzyme replacement therapy that is a monotherapy.* Find out if the NEX move is the right move for you.

*Not including pre-treatment or pre-medication.

IMPORTANT SAFETY INFORMATION (continued)

Infusion-Associated Reactions (IARs)

If you are taking NEXVIAZYME, you should know that severe IARs have occurred during and after NEXVIAZYME treatment. If severe IARs occur during your NEXVIAZYME infusion, your doctor may decide to immediately discontinue the infusion and provide appropriate medical care. If you have an acute underlying illness at the time of NEXVIAZYME infusion you may be at greater risk for IARs. If you have advanced Pompe disease you may have compromised heart and breathing function, which may put you at a higher risk of severe complications from IARs.

Please see additional Important Safety Information continued on the following pages and full Prescribing Information, including **Boxed WARNING**.

What is NEXVIAZYME?

NEXVIAZYME is an enzyme replacement therapy that is a monotherapy*. Find out if the NEX move is the right move for you.
**Not including pre-treatment or pre-medication.*

What does NEXVIAZYME do?

In a clinical study of 100 LOPD patients who had not been on treatment before, and who were given either NEXVIAZYME or alglucosidase alfa, NEXVIAZYME helped improve their breathing and walking distance compared to when they began the study.

After 49 weeks on NEXVIAZYME, compared to when they began treatment

People were able to improve their breathing capacity by an average of 2.9 percentage points in a breathing test:

- Those who took alglucosidase alfa improved their breathing by an average of 0.5 percentage points.
- This resulted in an average of 2.4 percentage points measurable improvement for people treated with NEXVIAZYME compared with people taking alglucosidase alfa, although NEXVIAZYME was not statistically superior.

People on NEXVIAZYME improved their walking distance by an average of 106 feet during a 6-minute walk test:

- Those taking alglucosidase alfa improved their walking distance by an average of 7.2 feet.
- People taking NEXVIAZYME walked an average of 98 feet farther than those who were taking alglucosidase alfa.

This measurement was not tested to determine statistical superiority of NEXVIAZYME to alglucosidase alfa.
The tests were given at the beginning of the study and again at the end, after 49 weeks of treatment.

NEXVIAZYME and safety

The information shown is highlighted from the Important Safety Information. Safety information can be found throughout this guide.
NEXVIAZYME has caused serious side effects, including:
- Hypersensitivity Reactions Including Anaphylaxis
- Infusion-Associated Reactions (IARs)
- Risk of Acute Cardiorespiratory Failure in Susceptible Patients

What are the possible side effects of NEXVIAZYME?

Over the 49-week study, people taking NEXVIAZYME had fewer serious side effects than those taking alglucosidase alfa. No one had to stop taking NEXVIAZYME because of side effects, while 4 people had to stop taking alglucosidase alfa. The most common side effects reported by people receiving NEXVIAZYME were headache, fatigue, diarrhea, nausea, joint pain, dizziness, muscle pain, itching, vomiting, shortness of breath, rash, "pins-and-needles" sensation, and hives. These are the most common side effects, but there are other possible side effects. You should always tell your doctor about any changes in the way you feel, even if it's not one of the listed side effects. **You can also report side effects at 1-800-FDA-1088 or www.fda.gov/medwatch.**

How does NEXVIAZYME work?

When you have LOPD, the body does not have enough of the enzyme that breaks down glycogen in your muscle cells, so the glycogen builds up and causes muscle damage. NEXVIAZYME has something called "high binding affinity" for a receptor in your muscle cell called M6P receptor. That receptor is like a lock on a door. M6P is like the key to opening that lock. NEXVIAZYME has "keys" on its surface that fit in the "lock." In fact, NEXVIAZYME has about 15 times the number of keys that alglucosidase alfa has. In a clinical study, NEXVIAZYME was not shown to be statistically superior to alglucosidase alfa.

How do I take NEXVIAZYME?

NEXVIAZYME is given every 2 weeks by intravenous (IV) infusion. The recommended dosage of NEXVIAZYME is either 20 mg or 40 mg for each kilogram of body weight—your healthcare provider will calculate the appropriate dosage for you. The infusion usually takes approximately 4-5 hours for those receiving 20 mg/kg and approximately 5-7 hours for those receiving 40 mg/kg. There could be additional time if you need any pretreatment. Also, infusion times may vary based on your response to therapy and comfort. Your healthcare provider will give you more details about what to expect during and after your infusion as well as how to prepare. You'll most likely want to bring a book, work, and/or electronic devices to make the most of your time. If you're switching to NEXVIAZYME from alglucosidase alfa, your treatment schedule may stay the same. *For any other questions, please contact your Sanofi CareConnect™ Personalized Support Services team at 1-800-745-4447, option 3.*

IMPORTANT SAFETY INFORMATION (continued)

Risk of Acute Cardiorespiratory Failure in Susceptible Patients

If you are likely to develop fluid volume overload, or have acute underlying breathing problems or compromised heart or breathing function that may require fluid restriction, there may be a risk of worsening of your heart or breathing status during NEXVIAZYME infusion. Your doctor may decide that close observation during NEXVIAZYME administration may be necessary.

Please see additional Important Safety Information continued on the following pages and full Prescribing Information, including Boxed WARNING.

IMPORTANT SAFETY INFORMATION AND INDICATION

IMPORTANT SAFETY INFORMATION

WARNING: SEVERE HYPERSENSITIVITY REACTIONS, INFUSION-ASSOCIATED REACTIONS, AND RISK OF ACUTE CARDIORESPIRATORY FAILURE IN SUSCEPTIBLE PATIENTS

Hypersensitivity Reactions Including Anaphylaxis

If you are taking NEXVIAZYME, you should know that severe and potentially life-threatening allergic-type reactions known as anaphylaxis and severe hypersensitivity reactions have occurred during and after NEXVIAZYME treatment. You should seek immediate medical care if signs and symptoms of anaphylaxis or hypersensitivity reactions occur. If such a reaction is severe enough, your doctor may decide to immediately discontinue the infusion and provide immediate medical care. Appropriate medical support measures may be administered during your infusion, and you may require close observation during and after NEXVIAZYME administration.

Infusion-Associated Reactions (IARs)

If you are taking NEXVIAZYME, you should know that severe IARs have occurred during and after NEXVIAZYME treatment. If severe IARs occur during your NEXVIAZYME infusion, your doctor may decide to immediately discontinue the infusion and provide appropriate medical care. If you have an acute underlying illness at the time of NEXVIAZYME infusion you may be at greater risk for IARs. If you have advanced Pompe disease you may have compromised heart and breathing function, which may put you at a higher risk of severe complications from IARs.

Risk of Acute Cardiorespiratory Failure in Susceptible Patients

If you are likely to develop fluid volume overload, or have acute underlying breathing problems or compromised heart or breathing function that may require fluid restriction, there may be a risk of worsening of your heart or breathing status during NEXVIAZYME infusion. Your doctor may decide that close observation during NEXVIAZYME administration may be necessary.

WARNINGS AND PRECAUTIONS

Hypersensitivity Reactions Including Anaphylaxis: See Boxed WARNING. Your doctor may decide to give you antihistamine, anti-fever and/or steroid medications before your infusions. Your doctor should consider the risks and benefits of restarting the infusion if you have a severe hypersensitivity reaction (including anaphylaxis) to NEXVIAZYME. If a mild or moderate hypersensitivity reaction occurs, your healthcare provider may slow the infusion rate or temporarily stop the infusion.

Infusion-Associated Reactions (IARs): See Boxed WARNING. Your doctor may decide to give you medications before your infusions to decrease the risk of IARs; however, IARs may still occur after receiving these medications. If mild or moderate IARs occur, your healthcare provider should consider decreasing the infusion rate or temporarily stopping the infusion which may help improve the symptoms.

Risk of Acute Cardiorespiratory Failure in Susceptible Patients: See Boxed WARNING.

ADVERSE REACTIONS

The most common adverse reactions (>5%) were headache, fatigue, diarrhea, nausea, joint pain, dizziness, muscle pain, itching, vomiting, shortness of breath, rash, “pins-and-needles” sensation, and hives.

INDICATION

NEXVIAZYME (avalglucosidase alfa-ngpt) is used for the treatment of patients 1 year of age and older with late-onset Pompe disease [lysosomal acid alpha-glucosidase (GAA) deficiency].

Please see full Prescribing Information for complete details, including Boxed WARNING.

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Nexviazyme®
(avalglucosidase alfa-ngpt)