RECLAIM YOUR FREEDOM WITH XENPOZYME—PROVEN TO DELIVER MULTIORGAN IMPROVEMENTS IN PEOPLE WITH ASMD

ASMD=acid sphingomyelinase deficiency.

Xenpozyme®
(olipudase alfa-rpcp)
For Injection, 20 mg

INDICATION

XENPOZYME® (olipudase alfa-rpcp) is indicated for treatment of non–central nervous system manifestations of acid sphingomyelinase deficiency (ASMD) in adult and pediatric patients.

IMPORTANT SAFETY INFORMATION

WARNING: SEVERE ALLERGIC REACTIONS

Allergic Reactions Including Anaphylaxis

Allergic reactions, including severe reactions that may be serious or life-threatening (known as anaphylaxis), have occurred during and after XENPOZYME treatment. Tell your healthcare provider right away if you develop any reactions, and seek immediate medical care if severe reactions occur. If a severe allergic reaction occurs, your doctor may decide to discontinue XENPOZYME immediately and provide appropriate medical care. Appropriate medical support measures may be administered, and you may require close observation during and after XENPOZYME administration.

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

ASMD IS A PROGRESSIVE DISEASE THAT CAN LEAD TO SERIOUS COMPLICATIONS

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WHAT IS ASMD?

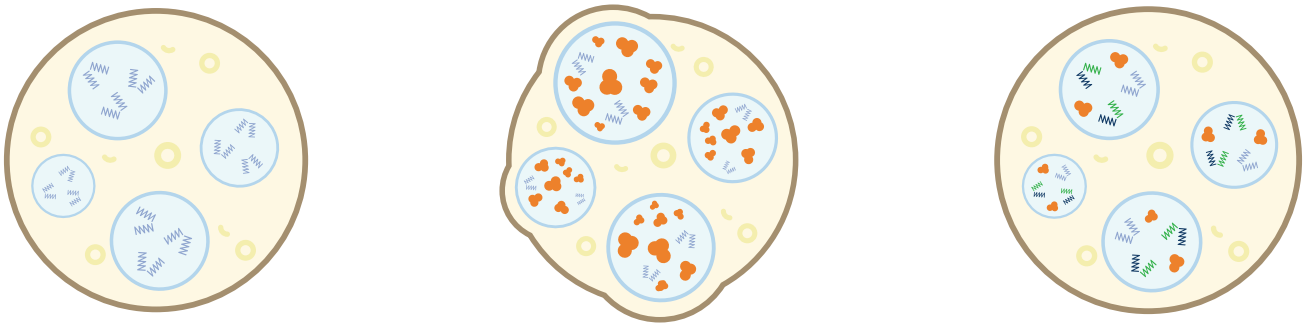
ASMD is an inherited condition with multiorgan symptoms that can worsen over time.

Historically known as Niemann-Pick disease types A, A/B, and B, ASMD is caused by reduced activity of an enzyme called acid sphingomyelinase (ASM). When you have this ASM enzyme deficiency, your body cannot adequately break down a substance in your cells called sphingomyelin.

Over time, ASMD can lead to multiorgan symptoms including:

- Difficulty breathing
- Enlarged spleen and/or liver
- Easy bleeding and bruising from low platelet count
- Growth delay in children

XENPOZYME TARGETS THE UNDERLYING CAUSE OF ASMD BY REPLACING THE DEFICIENT ASM ENZYME



Healthy cell

ASMD causes a buildup of sphingomyelin in the cells.

XENPOZYME replaces the ASM enzyme and helps reduce the buildup of sphingomyelin.

Lysosome

Accumulated sphingomyelin

ASM enzyme

ASM replacement **XENPOZYME**

- XENPOZYME is not expected to impact symptoms related to the central nervous system.

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

Allergic Reactions (Including Anaphylaxis) and Infusion-Associated Reactions (IARs)

See Boxed WARNING for more information. Your doctor may decide to give you antihistamine, anti-fever, and/or steroid medications before your infusions. Signs of allergic reactions and infusion-associated reactions (IARs) included hives, itchy skin, skin redness, rash, swelling underneath the skin, tender bumps under the skin, and localized swelling, as well as headache, vomiting, nausea, fever, and diarrhea.

Reactions may occur during and/or after the infusion. Tell your healthcare provider right away if you experience any reactions. Your healthcare provider may slow or stop the infusion or may lower the next dose.

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XENPOZYME IS THE FIRST AND ONLY DISEASE-SPECIFIC TREATMENT FOR ASMD

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IN ADULTS AND CHILDREN, XENPOZYME SHOWED IMPROVEMENTS ACROSS MULTIPLE ORGANS:

- ***Improved lung function***
- ***Reduced spleen and liver size***
- ***Raised platelet count***
- ***Improved growth patterns in children with growth delay***

WHEN STUDYING HOW XENPOZYME WORKED IN ADULTS AND CHILDREN IN THE CLINICAL TRIALS, THESE WERE KEY AREAS:

- ASMD can impact how the lungs work. The clinical trials in adults and children studied XENPOZYME to see whether it could help the lungs bring more oxygen into the bloodstream.*
- ASMD can cause the spleen and/or liver to be larger than normal, which can cause abdominal pain and loss of appetite. These trials studied XENPOZYME to see whether it could reduce spleen and/or liver size.
- ASMD can lead to a low platelet count, which can cause easy bleeding and bruising. These trials studied XENPOZYME to see whether it could increase platelet counts.
- Some children with ASMD may experience growth delay. The trials in children studied XENPOZYME to see if it could help improve growth patterns.

*As measured by DLco.
DLco=diffusing capacity of the lungs for carbon monoxide.

WITH XENPOZYME, BOTH ADULTS AND CHILDREN EXPERIENCED SUSTAINED AND CONTINUOUS IMPROVEMENTS IN MULTIPLE ORGANS.

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS (CONTINUED)

Elevated Transaminases Levels

XENPOZYME may be associated with elevated liver enzymes (known as transaminases) within 24 to 48 hours after infusion. Your doctor should check your liver enzyme levels with a blood test:

- within one month before starting XENPOZYME;
- within 72 hours before any infusion during the dose escalation phase, or before your next scheduled XENPOZYME infusion if you missed a dose.

Based on the results of your blood tests, your doctor may make changes to your dose or infusion schedule. Upon reaching the recommended maintenance dose, your doctor may continue to monitor your liver enzyme levels.

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TARGET THE UNDERLYING CAUSE OF ASMD AND MOVE FORWARD WITH XENPOZYME

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BRADLEY, living with ASMD.

CLINICAL TRIAL IN ADULTS:

- The safety and effectiveness of XENPOZYME were studied in a clinical trial of 31 adults with ASMD type B or type A/B aged 18 to 66 years.
- 13 adults were randomized to receive XENPOZYME and 18 adults received placebo. The clinical trial was blinded, meaning the participants and their doctors did not know if they were receiving placebo or receiving XENPOZYME.
- All adults were followed for 1 year, after which those receiving placebo were offered XENPOZYME.
- 17 of 18 adults previously receiving placebo and 13 of 13 adults previously treated with XENPOZYME for 1 year started or continued treatment with XENPOZYME, respectively, for up to 4 years.

IN ADULTS, XENPOZYME:

- ***Improved lung function***
- ***Reduced spleen and liver size***
- ***Raised platelet count***

XENPOZYME HELPED ADULTS ACHIEVE SIGNIFICANT IMPROVEMENTS IN MULTIPLE ORGANS.

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS (CONTINUED)

Risk to Unborn Babies

Starting or increasing the dose of XENPOZYME is not recommended in a pregnant female as it may cause harm (birth defects) to the developing baby. If you are pregnant or plan to become pregnant, tell your doctor right away.

If you are a female of reproductive potential, your doctor will verify your pregnancy status before you start treatment with XENPOZYME. You should use effective contraception during XENPOZYME treatment and for 14 days after your last dose if XENPOZYME is discontinued.

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IN ADULTS, XENPOZYME DEMONSTRATED SIGNIFICANT AND SUSTAINED IMPROVEMENTS ACROSS MULTIPLE ORGANS

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After 1 year of treatment, when compared to baseline:

24% SIGNIFICANT IMPROVEMENT IN LUNG FUNCTION* WITH XENPOZYME

VS 3% WITH PLACEBO

*As measured by DLco.

39% SIGNIFICANT REDUCTION IN SPLEEN VOLUME WITH XENPOZYME

VS +0.5% WITH PLACEBO

27% SIGNIFICANT REDUCTION IN LIVER VOLUME WITH XENPOZYME *VS 2% WITH PLACEBO*

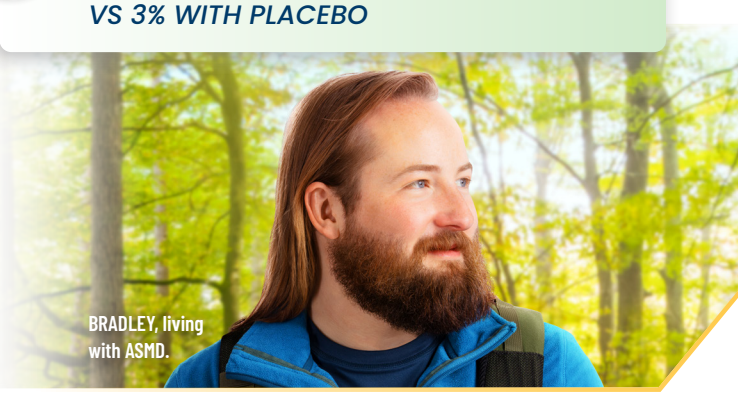
Adults experienced improvements in the following exploratory endpoints:

- **Mean ALT decreased 37% vs baseline**
- **Mean AST decreased 36% vs baseline**

This study was not designed to evaluate impact on liver function. Therefore, no conclusions can be made regarding the numerical improvement in ALT and AST.

18% SIGNIFICANT INCREASE IN PLATELET COUNT WITH XENPOZYME

VS 3% WITH PLACEBO



AT 2 YEARS, XENPOZYME DEMONSTRATED SUSTAINED AND CONTINUOUS IMPROVEMENTS IN MULTIPLE ORGANS

Adults in the original XENPOZYME group demonstrated improvements from baseline to 2 years.

- *34% improvement in lung function* (n=5)*
- *48% reduction in spleen volume (n=9)*
- *32% reduction in liver volume (n=9)*
- *24% increase in platelet count (n=9)*

*As measured by DLco.

ALT=alanine aminotransferase; AST=aspartate aminotransferase.

IMPORTANT SAFETY INFORMATION

ADVERSE REACTIONS

- Most frequently reported adverse drug reactions in adults (incidence ≥10%) were headache, cough, diarrhea, low blood pressure, and redness in the eye.
- Most frequently reported adverse drug reactions in pediatric patients (incidence ≥20%) were fever, cough, diarrhea, runny nose, abdominal pain, vomiting, headache, hives, nausea, rash, joint pain, itchy skin, fatigue, and sore throat.

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THE SAFETY OF XENPOZYME WAS STUDIED IN A CLINICAL TRIAL IN ADULTS

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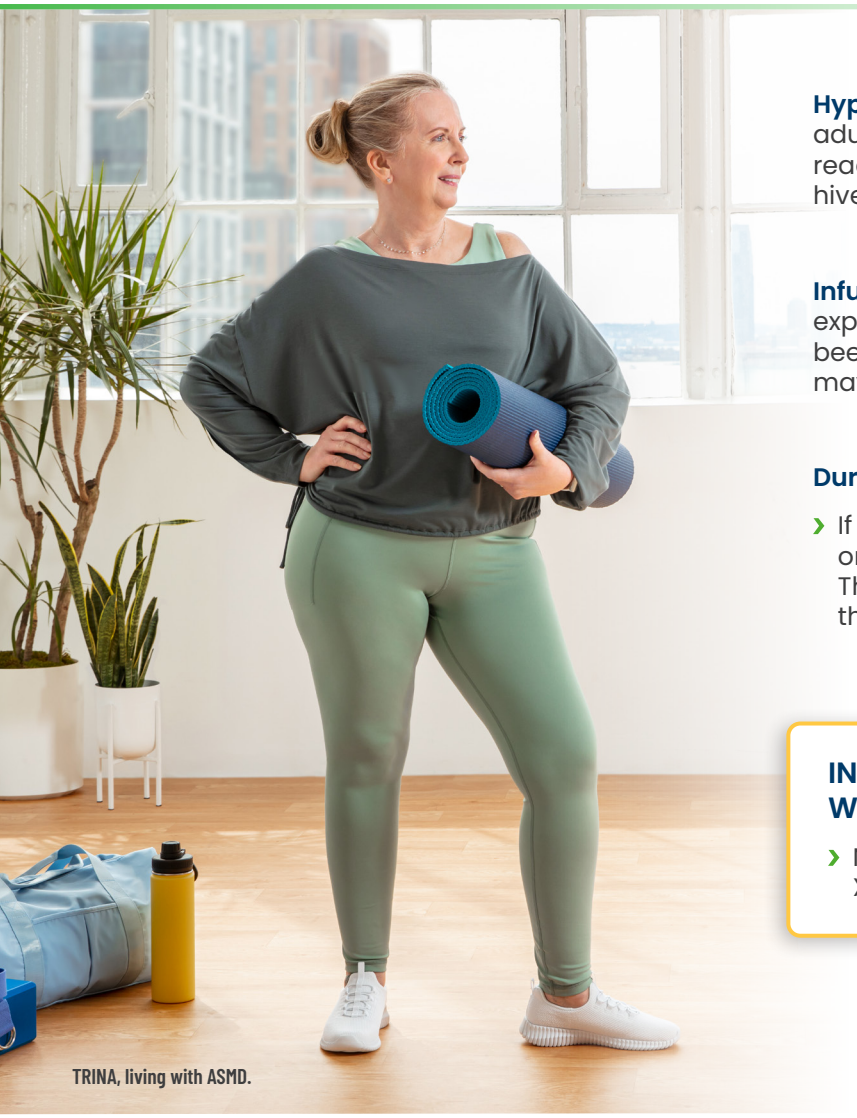
ADULTS: The most frequently reported side effects in adults (incidence ≥10%) were headache (54%), cough (31%), diarrhea (15%), low blood pressure (15%), and redness in the eye (15%).



TRINA, living with ASMD.

Hypersensitivity reactions: In the clinical trials, some adults experienced mild or moderate hypersensitivity reactions associated with the XENPOZYME infusion, such as hives, redness of the skin, or itchy skin.

Infusion-associated reactions (IARs): Some adults experienced side effects in the clinical trials that may have been associated with the XENPOZYME infusion. Reactions may occur during and after the infusion.

During the infusion, the doctor will monitor for IARs.

- If you are having a reaction to the infusion, whether mild or severe, tell your doctor or infusion nurse right away. The doctor may slow or stop the infusion and may lower the next dose.

IN THE CLINICAL TRIALS, THE MAJORITY OF IARs WITH XENPOZYME WERE MILD TO MODERATE

- No one in the clinical trials stopped receiving XENPOZYME due to side effects.

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

Allergic Reactions (Including Anaphylaxis) and Infusion-Associated Reactions (IARs)

See Boxed WARNING for more information. Your doctor may decide to give you antihistamine, anti-fever, and/or steroid medications before your infusions. Signs of allergic reactions and infusion-associated reactions (IARs) included hives, itchy skin, skin redness, rash, swelling underneath the skin, tender bumps under the skin, and localized swelling, as well as headache, vomiting, nausea, fever, and diarrhea.

Reactions may occur during and/or after the infusion. Tell your healthcare provider right away if you experience any reactions. Your healthcare provider may slow or stop the infusion or may lower the next dose.

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IN CHILDREN, XENPOZYME WAS PROVEN TO SHOW SUSTAINED AND CONTINUOUS IMPROVEMENTS ACROSS MULTIPLE ORGANS

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CLINICAL TRIAL IN CHILDREN:

- The safety and effectiveness of XENPOZYME were evaluated in children with ASMD type B or type A/B who were <18 years old (7 children from 2 to <12 years old, and 1 child <2 years old) who all received XENPOZYME over 64 weeks in a clinical trial.

IN CHILDREN, XENPOZYME:

- *Improved lung function*
- *Reduced spleen and liver size*
- *Raised platelet count*
- *Improved growth patterns in children with growth delay*

AFTER 1 YEAR OF TREATMENT, CHILDREN RECEIVING XENPOZYME EXPERIENCED IMPROVEMENTS IN THE FOLLOWING EXPLORATORY ENDPOINTS FROM BASELINE:

46% IMPROVEMENT IN LUNG FUNCTION* (n=3)

*As measured by DLco.

47% REDUCTION IN SPLEEN VOLUME (n=8)

38% REDUCTION IN LIVER VOLUME (n=8)

Children experienced improvements in the following exploratory endpoints:

- **Mean ALT decreased 53% vs baseline**
- **Mean AST decreased 47% vs baseline**

This study was not designed to evaluate impact on liver function. Therefore, no conclusions can be made regarding the numerical improvement in ALT and AST.

38% INCREASE IN PLATELET COUNT (n=7)

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS (CONTINUED)

Elevated Transaminases Levels

XENPOZYME may be associated with elevated liver enzymes (known as transaminases) within 24 to 48 hours after infusion. Your doctor should check your liver enzyme levels with a blood test:

- within one month before starting XENPOZYME;
- within 72 hours before any infusion during the dose escalation phase, or before your next scheduled XENPOZYME infusion if you missed a dose.

Based on the results of your blood tests, your doctor may make changes to your dose or infusion schedule. Upon reaching the recommended maintenance dose, your doctor may continue to monitor your liver enzyme levels.

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IN CHILDREN, XENPOZYME WAS PROVEN TO SHOW IMPROVEMENTS ACROSS MULTIPLE ORGANS

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XENPOZYME IMPROVED GROWTH AT 1 YEAR

IMPROVEMENT IN GROWTH FOR CHILDREN EXPERIENCING GROWTH DELAY

XENPOZYME improved growth delay after 1 year of treatment. This was measured by height Z-scores. The average improvement in height Z-scores from baseline was 0.5 (n=7).

XENPOZYME DEMONSTRATED SUSTAINED AND CONTINUOUS LONG-TERM IMPROVEMENTS IN MULTIPLE ORGANS

- All children from the clinical trial continued treatment with XENPOZYME in the Long-Term Trial and were treated for 2.5 to 3.2 years.

LONG-TERM TRIAL RESULTS

- Children continued to **experience improvement in lung function, reduction in spleen volume, reduction in liver volume, and increase in platelet count.**
- Children continued to experience **improvement in height Z-scores** when evaluated through 24 months.
- Children experienced **improvement in bone age**. This was assessed by hand x-ray.
  - At the start of the clinical trial in children, the average bone age was delayed by a little over 2 years. In the Long-Term Trial, after 2 years of treatment with XENPOZYME, the average bone age improved by 1 year. This means **bone age became closer to chronological age.**

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS (CONTINUED)

Risk to Unborn Babies

Starting or increasing the dose of XENPOZYME is not recommended in a pregnant female as it may cause harm (birth defects) to the developing baby. If you are pregnant or plan to become pregnant, tell your doctor right away.

If you are a female of reproductive potential, your doctor will verify your pregnancy status before you start treatment with XENPOZYME. You should use effective contraception during XENPOZYME treatment and for 14 days after your last dose if XENPOZYME is discontinued.

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THE SAFETY OF XENPOZYME WAS STUDIED IN 2 CLINICAL TRIALS IN CHILDREN

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CHILDREN: The most frequently reported side effects in children (incidence ≥20%) were fever (100%), cough (75%), diarrhea (75%), runny nose (75%), abdominal pain (63%), vomiting (50%), headache (50%), hives (50%), nausea (38%), rash (38%), joint pain (38%), itchy skin (25%), fatigue (25%), and sore throat (25%).

- Serious anaphylactic reactions were reported in 2 (25%) children treated with XENPOZYME.

Hypersensitivity reactions: In the clinical trials, some children experienced mild, moderate, or severe hypersensitivity reactions associated with the XENPOZYME infusion, such as hives, redness of the skin, or itchy skin.

IARs: Some children experienced side effects in the clinical trials that may have been associated with the XENPOZYME infusion. Reactions may occur during and after the infusion.

During the infusion, the doctor will monitor for IARs.

- If you or your child is having a reaction to the infusion, whether mild or severe, tell your doctor or infusion nurse right away. The doctor may slow or stop the infusion and may lower the next dose.

IN THE CLINICAL TRIALS, THE MAJORITY OF IARs WITH XENPOZYME WERE MILD TO MODERATE

- No one in the clinical trials stopped receiving XENPOZYME due to side effects.

LUKE, living with ASMD, and his mom, Nicole.

IMPORTANT SAFETY INFORMATION

ADVERSE REACTIONS

- Most frequently reported adverse drug reactions in adults (incidence ≥10%) were headache, cough, diarrhea, low blood pressure, and redness in the eye.
- Most frequently reported adverse drug reactions in pediatric patients (incidence ≥20%) were fever, cough, diarrhea, runny nose, abdominal pain, vomiting, headache, hives, nausea, rash, joint pain, itchy skin, fatigue, and sore throat.

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THIS WAY FORWARD TO STARTING XENPOZYME

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BEFORE INITIATING XENPOZYME

- XENPOZYME dosage initiation or escalation, at any time during pregnancy, is not recommended.
  - If you are a female of reproductive potential, your doctor will verify your pregnancy status before starting treatment with XENPOZYME.
  - Use effective contraception during treatment with XENPOZYME and for 14 days after the last dose if XENPOZYME is discontinued.
  - If you are pregnant or plan to become pregnant, tell your doctor right away.
- Your doctor will order a baseline liver enzyme level measurement for you or your child within 1 month prior to the start of treatment.
- Prior to infusion, your doctor may decide to pretreat you or your child with anti-fever, anti-allergy, and/or steroid medications.

XENPOZYME DOSING

Treatment with XENPOZYME takes place in 2 phases:

FIRST PHASE IS CALLED DOSE ESCALATION
You or your child will start on a low dose that will gradually increase throughout the dose escalation phase. This will last at least 14 weeks for adults and at least 16 weeks for children.*

Why dose escalation? Gradual dose escalation is essential and may reduce the risk of IARs and elevated liver enzyme levels when first starting treatment.

Where does dose escalation take place? The dose escalation period takes place in a clinical setting to manage for the possibility of severe reactions.

SECOND PHASE IS CALLED MAINTENANCE

After dose escalation, the target maintenance dose is 3 mg/kg.

Why ongoing maintenance? In people with ASMD, the body is unable to make enough of the ASM enzyme; therefore, it is important to keep taking XENPOZYME every 2 weeks.

Can infusions take place at home? Once you or your child starts receiving the maintenance dose, there is a potential option of receiving XENPOZYME at home if your doctor recommends it.

*In clinical trials, all but 1 of the children completed the dose escalation up to the target maintenance dose of 3 mg/kg within 22 weeks.

XENPOZYME KEEPS WORKING WHEN YOU KEEP TAKING IT REGULARLY.

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MONITORING FOR LIVER ENZYME LEVELS DURING INFUSIONS

- **During the dose escalation phase,** your doctor will regularly order blood tests to monitor how the liver is working. If liver enzymes are elevated, the doctor may delay an infusion, repeat a dose, or lower the dose for the next infusion.
- **During the maintenance phase,** upon reaching the recommended maintenance dose, testing for liver enzyme levels is recommended to be continued as part of routine clinical management of ASMD.

BE SURE TO KEEP ALL YOUR INFUSION APPOINTMENTS. IF YOU MISS INFUSIONS, YOU MAY NEED TO RETURN TO DOSE ESCALATION. DOSE ESCALATION SHOULD TAKE PLACE IN A CLINICAL SETTING.

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INDICATION

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WARNINGS AND PRECAUTIONS

Allergic Reactions (Including Anaphylaxis) and Infusion-Associated Reactions (IARs)

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Based on the results of your blood tests, your doctor may make changes to your dose or infusion schedule. Upon reaching the recommended maintenance dose, your doctor may continue to monitor your liver enzyme levels.

Risk to Unborn Babies

Starting or increasing the dose of XENPOZYME is not recommended in a pregnant female as it may cause harm (birth defects) to the developing baby. If you are pregnant or plan to become pregnant, tell your doctor right away.

If you are a female of reproductive potential, your doctor will verify your pregnancy status before you start treatment with XENPOZYME. You should use effective contraception during XENPOZYME treatment and for 14 days after your last dose if XENPOZYME is discontinued.

ADVERSE REACTIONS

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careconnect™
PERSONALIZED SUPPORT SERVICES

CareConnect Personalized Support Services provides personalized support to eligible individuals. From diagnosis and treatment journey to insurance coverage and community connections, CareConnect has someone available to help.

SPEAKING ASMD

ASMD can be hard to understand or explain. CareConnect offers disease and treatment education—both in-person and virtually—for you, family members, and important members of your community.

CARE COORDINATION

It is important to stay connected to ASMD healthcare providers. CareConnect can assist you in finding appropriate medical facilities. If you relocate or travel, CareConnect can also help with logistics.

INSURANCE COVERAGE

It is important to understand insurance coverage. CareConnect can help eligible patients navigate the healthcare system and know more about their options.

FINANCIAL ASSISTANCE

CareConnect can help eligible patients understand and manage treatment costs, follow up on insurance claims, and find assistance programs.

Access personalized support and resources at CareConnectPSS.com
or call **1-800-745-4447** (toll free), Option 3,
or email **Info@CareConnectPSS.com.**

LEARN MORE AT CARECONNECTPSS.COM

XENPOZYME IS THE FIRST AND ONLY DISEASE-SPECIFIC TREATMENT FOR ASMD

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XENPOZYME WAS PROVEN TO SHOW IMPROVEMENTS ACROSS MULTIPLE ORGANS IN ADULTS AND CHILDREN

After 1 year of treatment in the clinical trials, when compared to baseline, **XENPOZYME:**

Improved lung function*

24% significant improvement in adults (n=12) vs 3% with placebo (n=17)

46% improvement in children (n=3)

*As measured by DL_{CO}.

Reduced spleen enlargement

39% significant reduction in adults (n=13) vs +0.5% with placebo (n=17)

47% reduction in children (n=8)

Reduced liver enlargement

27% significant reduction in adults (n=12) vs 2% with placebo (n=17)

38% reduction in children (n=8)

Raised platelet count

18% significant increase in adults (n=13) vs 3% with placebo (n=16)

38% increase in children (n=7)

Improved growth patterns in children with growth delay (n=7)

XENPOZYME DEMONSTRATED SUSTAINED AND CONTINUOUS LONG-TERM IMPROVEMENTS IN MULTIPLE ORGANS

- In the clinical trials, XENPOZYME demonstrated sustained and continuous improvements in adults and in children for up to 2 years.
- The safety of XENPOZYME was studied across 3 clinical trials in adults and children.

TARGET THE UNDERLYING CAUSE, RECLAIM YOUR FREEDOM.

LEARN MORE AT XENPOZYME.COM

INDICATION

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