RETHYMIC®
allogeneic processed thymus tissue-agdc

HELP YOUR CHILD WITH CONGENITAL ATHYMIA

Discover the wonder of childhood

RETHYMIC is the first and only FDA-approved tissue-based treatment for congenital athymia. It is engineered to help children develop an immune system sufficient to fight infections.

RETHYMIC is not indicated for the treatment of patients with severe combined immunodeficiency.

Jada, a child with congenital athymia.

INDICATION

RETHYMIC® is indicated for immune reconstitution in pediatric patients with congenital athymia.

RETHYMIC is not for use in patients who have been diagnosed with severe combined immunodeficiency (SCID).

IMPORTANT SAFETY INFORMATION

Infection Control: Immune reconstitution sufficient to protect from infection usually develops between 6-12 months after treatment with RETHYMIC. For some children, it may take up to 2 years. Taking medications that prevent infection and other infection control measures, such as hand washing and isolation, should be continued until your child's doctor confirms that immune function has been reconstituted through immune tests and the criteria for discontinuing certain medications have been met. Immediately report signs and symptoms of infection, such as fever, to your child's doctor.

Please see additional Important Safety Information and the QR code to the full Prescribing Information on pages 10 & 11, or visit RETHYMIC.com/prescribing-information.

Scan the QR code to learn about our patient support program, or visit RETHYMIC.com

What is RETHYMIC?

RETHYMIC is the first and only treatment for congenital athymia

RETHYMIC is an FDA-approved tissue-based treatment for congenital athymia. It is engineered to help children develop an immune system sufficient to fight infections.

IMPORTANT SAFETY INFORMATION (cont'd)

Graft versus Host Disease (GVHD): RETHYMIC may cause or make pre-existing GVHD worse. Your child will be monitored for GVHD and treated if needed. Symptoms of GVHD may include fever, rash, swollen lymph nodes, inflammation of the digestive system, and/or diarrhea.

RETHYMIC®
allogeneic processed thymus tissue-agdc

RETHYMIC is a one-time treatment administered via a single surgical procedure

RETHYMIC is implanted in one, or both if necessary, of the thighs of a child with congenital athymia. The thigh muscle is used because its rich supply of blood provides oxygen and nutrients to RETHYMIC. After it is implanted, it is believed that the child's pre-T cells migrate to RETHYMIC where they develop into T cells that are sufficient to fight infections.

What is congenital athymia?

Congenital athymia is a rare immune condition that requires children and often their families to live in strict isolation due to a lack of a functioning immune system.

Children with congenital athymia are born without a functioning thymus. The thymus is an organ that sits on top of the heart and plays an important role in how the immune system works.

Jada, a child with congenital athymia.

IMPORTANT SAFETY INFORMATION (cont'd)

Autoimmune Disorders: Autoimmune-related side effects (when your immune system attacks healthy cells by mistake) occurred in patients treated with RETHYMIC. These included low platelets, white blood cells, or red blood cells; protein in the urine; hair loss; poor thyroid function; inflammation of the liver, joints, or spinal cord; loss of pigment in the skin, eyes and hair; overactive thyroid function; and loss of function of the ovaries. Your doctor will monitor your child regularly.

Please see additional Important Safety Information and the QR code to the full Prescribing Information on pages 10 & 11, or visit RETHYMIC.com/prescribing-information.

How is RETHYMIC made?

Unlike a transplant, RETHYMIC is manufactured for one child at a time through a complex process using donor thymus tissue

Donation

When an infant 9 months of age or younger has cardiac surgery, some thymus tissue may need to be removed to access the heart. With consent of the infant donor's parents or guardian, **the thymus tissue is donated to make RETHYMIC.**

Unlike many other medications, RETHYMIC is not an off-the-shelf product. **The tissue from a single pediatric donor allows for the manufacturing of RETHYMIC for one child.**

The availability of RETHYMIC is dependent on multiple factors, including the size of the thymus tissue that is donated.

IMPORTANT SAFETY INFORMATION (cont'd)

Kidney Disease: Children with kidney disease have a higher risk of death when treated with RETHYMIC.

Cytomegalovirus (CMV) Infection: In clinical studies, 4 out of 4 patients with CMV infection prior to treatment with RETHYMIC died.

Manufacturing

The amount of time the engineering process takes depends on multiple factors and can be completed between **12 and 21 days.**

During this 12- to 21-day engineering process, most of the donor's pre-T cells are removed and **the tissue is tested repeatedly to ensure the product meets FDA safety standards.** Through this process, the donor thymus tissue becomes the FDA-approved treatment, RETHYMIC.

Implantation

The available dosage is based on the donor thymus tissue, and the amount implanted is based on the recipient's body surface area.

Once released from the manufacturing facility, **RETHYMIC must be implanted within a limited time frame at the treatment center.**

The manufacturing of RETHYMIC must be carefully coordinated with the preparation of a potential recipient.

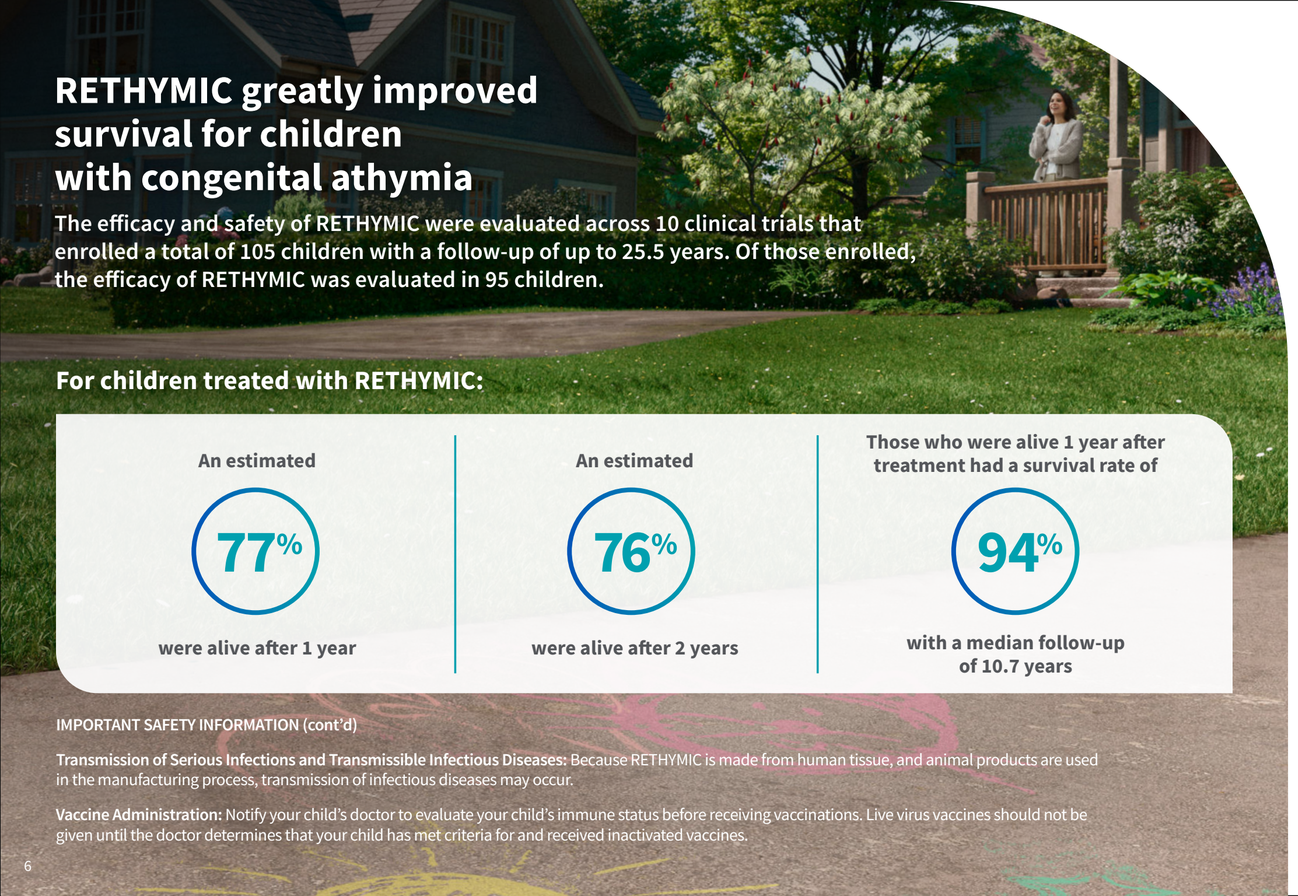
Brynlee, a child with congenital athymia.

IMPORTANT SAFETY INFORMATION (cont'd)

Cancer: Due to your child's weakened immune system, there is an increased risk of developing blood cancer. Your child's doctor will monitor your child through testing for Epstein-Barr virus and CMV, which are two viruses that can cause cancer.

Please see additional Important Safety Information and the QR code to the full Prescribing Information on pages 10 & 11, or visit RETHYMIC.com/prescribing-information.

RETHYMIC®
allogeneic processed thymus tissue-agdc



RETHYMIC greatly improved survival for children with congenital athymia

The efficacy and safety of RETHYMIC were evaluated across 10 clinical trials that enrolled a total of 105 children with a follow-up of up to 25.5 years. Of those enrolled, the efficacy of RETHYMIC was evaluated in 95 children.

For children treated with RETHYMIC:

An estimated **77%** were alive after 1 year

An estimated **76%** were alive after 2 years

Those who were alive 1 year after treatment had a survival rate of **94%** with a median follow-up of 10.7 years

IMPORTANT SAFETY INFORMATION (cont'd)

Transmission of Serious Infections and Transmissible Infectious Diseases: Because RETHYMIC is made from human tissue, and animal products are used in the manufacturing process, transmission of infectious diseases may occur.

Vaccine Administration: Notify your child's doctor to evaluate your child's immune status before receiving vaccinations. Live virus vaccines should not be given until the doctor determines that your child has met criteria for and received inactivated vaccines.

RETHYMIC®
allogeneic processed thymus tissue-agdc

RETHYMIC significantly reduced the number of infections over time:

38% **fewer children experienced an infection between 6 and 12 months after treatment with RETHYMIC vs the first 6 months after treatment**

In a 2-year analysis, fewer children experienced an infection and the average number of infections per child decreased in the second year after treatment compared to the first year after treatment.

The safety of RETHYMIC was demonstrated in 105 children across 10 clinical trials

The most common side effects of RETHYMIC were:

- Hypertension (high blood pressure)
- Cytokine release syndrome (overactive immune system)
- Hypomagnesemia (low magnesium)
- Rash
- Renal impairment/failure (decrease of kidney function)
- Thrombocytopenia (low platelets)
- Graft versus host disease (GVHD) (a condition in which a person's T cells attack their own body)

Of the 105 children in clinical studies, 29 died, including 23 in the first year. The majority of deaths in the first year after receiving RETHYMIC were due to infections.

IMPORTANT SAFETY INFORMATION (cont'd)

Anti-HLA Antibodies: Before receiving RETHYMIC, your child will be tested for HLA antibodies, which are proteins that may be present in your child's blood. If your child has these antibodies, your child should receive RETHYMIC from a specific donor, which will be determined by your child's doctor.

Please see additional Important Safety Information and the QR code to the full Prescribing Information on pages 10 & 11, or visit RETHYMIC.com/prescribing-information.

The treatment journey

RETHYMIC is currently only available at Duke Children's Hospital in Durham, North Carolina

Your child's healthcare provider will need to reach out to Duke Children's Hospital to begin the process of referring them for RETHYMIC.

Consider speaking to your child's healthcare provider about enrolling in RETHYMIC Connect™ while they start the referral process.

Sumitomo Pharma America, Inc. and RETHYMIC Connect are not responsible for treatment decisions or timing for treatment.

IMPORTANT SAFETY INFORMATION (cont'd)

HLA Typing: If your child received a hematopoietic cell transplantation (HCT) or a solid organ transplant, testing to match your child with RETHYMIC from a compatible donor is required. Children who have received an HCT are at an increased risk of developing GVHD after RETHYMIC if the HCT donor does not fully match with RETHYMIC.

Deaths: Of the 105 children who participated in the clinical studies, 29 patients died, including 23 in the first year after implantation of RETHYMIC.

Brynlee, a child with congenital athymia.

RETHYMIC®
allogeneic processed thymus tissue-agdc

Proper post-treatment care is critical to protect your child

RETHYMIC needs time to help develop an immune system sufficient to protect from infections, which usually develops between 6 to 12 months after treatment with RETHYMIC. For some children, it may take up to 2 years.

Your child will remain immune compromised while RETHYMIC starts to work, so to keep them safe, life immediately after treatment will have to look very similar to life before it. Careful monitoring and isolation are required to ensure your child avoids infections after treatment with RETHYMIC. Your child should also be monitored for other complications, like GVHD and autoimmune disorders.

Work with your child's healthcare provider to determine when infection prevention measures can be lifted.

IMPORTANT SAFETY INFORMATION (cont'd)

The most common side effects are high blood pressure, cytokine release syndrome, rash, low magnesium, decrease in kidney function, low platelets, and GVHD.

These are not all the possible side effects of RETHYMIC. Talk to your child's doctor about any side effect that bothers your child or does not go away.

Please see additional Important Safety Information and the QR code to the full Prescribing Information on pages 10 & 11, or visit RETHYMIC.com/prescribing-information.

RETHYMIC®
allogeneic processed thymus tissue-agdc

INDICATION

RETHYMIC® is indicated for immune reconstitution in pediatric patients with congenital athymia.

RETHYMIC is not for use in patients who have been diagnosed with severe combined immunodeficiency (SCID).

IMPORTANT SAFETY INFORMATION

Infection Control: Immune reconstitution sufficient to protect from infection usually develops between 6-12 months after treatment with RETHYMIC. For some children, it may take up to 2 years. Taking medications that prevent infection and other infection control measures, such as hand washing and isolation, should be continued until your child's doctor confirms that immune function has been reconstituted through immune tests and the criteria for discontinuing certain medications have been met. Immediately report signs and symptoms of infection, such as fever, to your child's doctor.

Graft versus Host Disease (GVHD): RETHYMIC may cause or make pre-existing GVHD worse. Your child will be monitored for GVHD and treated if needed. Symptoms of GVHD may include fever, rash, swollen lymph nodes, inflammation of the digestive system, and/or diarrhea.

Autoimmune Disorders: Autoimmune-related side effects (when your immune system attacks healthy cells by mistake) occurred in patients treated with RETHYMIC. These included low platelets, white blood cells, or red blood cells; protein in the urine; hair loss; poor thyroid function; inflammation of the liver, joints, or spinal cord; loss of pigment in the skin, eyes and hair; overactive thyroid function; and loss of function of the ovaries. Your doctor will monitor your child regularly.

Kidney Disease: Children with kidney disease have a higher risk of death when treated with RETHYMIC.

Cytomegalovirus (CMV) Infection: In clinical studies, 4 out of 4 patients with CMV infection prior to treatment with RETHYMIC died.

Cancer: Due to your child's weakened immune system, there is an increased risk of developing blood cancer. Your child's doctor will monitor your child through testing for Epstein-Barr virus and CMV, which are two viruses that can cause cancer.

IMPORTANT SAFETY INFORMATION (cont'd)

Transmission of Serious Infections and Transmissible Infectious Diseases: Because RETHYMIC is made from human tissue, and animal products are used in the manufacturing process, transmission of infectious diseases may occur.

Vaccine Administration: Notify your child's doctor to evaluate your child's immune status before receiving vaccinations. Live virus vaccines should not be given until the doctor determines that your child has met criteria for and received inactivated vaccines.

Anti-HLA Antibodies: Before receiving RETHYMIC, your child will be tested for HLA antibodies, which are proteins that may be present in your child's blood. If your child has these antibodies, your child should receive RETHYMIC from a specific donor, which will be determined by your child's doctor.

HLA Typing: If your child received a hematopoietic cell transplantation (HCT) or a solid organ transplant, testing to match your child with RETHYMIC from a compatible donor is required. Children who have received an HCT are at an increased risk of developing GVHD after RETHYMIC if the HCT donor does not fully match with RETHYMIC.

Deaths: Of the 105 children who participated in the clinical studies, 29 patients died, including 23 in the first year after implantation of RETHYMIC.

The most common side effects are high blood pressure, cytokine release syndrome, rash, low magnesium, decrease in kidney function, low platelets, and GVHD.

These are not all the possible side effects of RETHYMIC. Talk to your child's doctor about any side effect that bothers your child or does not go away. You are encouraged to report side effects to the FDA at 1-800-FDA-1088 or www.fda.gov/safety/medwatch

Please scan the QR code to see the full Prescribing Information, or visit RETHYMIC.com/prescribing-information

Supporting children and their families

RETHYMIC
(allogeneic processed thymus tissue-agdc)
connect

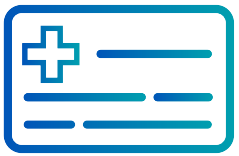
Enrolling in the RETHYMIC Connect™ Patient Support Program will give you and your family access to **educational resources** and, if eligible, **financial assistance** as you navigate the congenital athymia journey. RETHYMIC Connect is available to patients with any type of insurance—including commercial plans, Medicare, or Medicaid—as well as patients who are underinsured or have no insurance coverage.

Dedicated care team

- Your Support Liaison will help you understand your child's diagnosis
- Your Access Specialist can help you navigate insurance benefits and financial assistance

Access to exclusive resources

- Document organizer
- *Sadie's Search*, a storybook written specifically with your child in mind
- Interactive T-cell progress tracker
- Activity book
- And more!



Co-pay program

- The RETHYMIC Connect™ Commercial Co-Pay Program can help caregivers of eligible commercially-insured patients in the US and US territories
- You may receive co-pay assistance for medication-related out-of-pocket costs for RETHYMIC

Scan the QR code to start your enrollment, or visit RETHYMIC.com

Call 877-RETHYMC (877-738-4962) to get connected to personalized support.
Support is available Monday–Friday, 8:00 AM to 8:00 PM ET.

Please see full Important Safety Information and the QR code to the full Prescribing Information on pages 10 & 11, or visit RETHYMIC.com/prescribing-information.

Sumitomo Pharma