RETHYMIC®
allogeneic processed thymus tissue-agdc

RETHYMIC (allogeneic processed thymus tissue-agdc) connect

# Patient Enrollment Form

This form is intended for US patients only.

**FAX: 888-936-8859**

**RETHYMIC Connect™ is a program that provides patients and their families with personalized support as they navigate the treatment journey.**

**1.** To enroll, please complete the form and either fax it to 888-936-8859 or mail it to RETHYMIC Connect, PO Box 220701, Charlotte, NC 28222.

**2.** Before submitting the form, please ensure all required signatures have been obtained by both the patient's provider and their parent/caregiver/legal guardian.

For assistance, call RETHYMIC Connect toll-free at **877-RETHYMC (877-738-4962)**, Monday–Friday, 8:00 AM to 8:00 PM ET.
**Sumitomo Pharma America, Inc. and RETHYMIC Connect are not responsible for treatment decisions or timing for treatment.**

## PATIENT AND PARENT/LEGAL GUARDIAN INFORMATION

Patient Name: _____ Gender: ☐ Male ☐ Female Date of Birth: _____

Parent/Legal Guardian Name: _____ Relationship: ☐ Parent ☐ Power of Attorney ☐ Other

Street Address: _____ City: _____ State: _____ Zip: _____

Primary Phone #: _____ Secondary Phone #: _____

Best time to contact (day/time): _____ Can we send texts? ☐ Yes ☐ No Email: _____

Patient Primary Diagnosis ICD-10 Code: ☐ D82.1 Di George's Syndrome ☐ Other (include ICD-10 code): _____

Patient Allergies: _____ ☐ No known allergies

## PARENT/CAREGIVER/LEGAL GUARDIAN INSURANCE INFORMATION

**Please include copies of the front and back of the primary and, if applicable, secondary insurance cards.**

Primary Insurance: _____ Policy Holder Name: _____

Policy ID #: _____ Group #: _____ Phone #: _____

Secondary Insurance: _____ Policy Holder Name: _____

Policy ID #: _____ Group #: _____ Phone #: _____

## PATIENT SUPPORT PROGRAMS

**Please select the program(s) you would like to apply (your patient) for. We'll review eligibility for the selected program(s).**

RETHYMIC is surgically implanted in Durham, North Carolina. Is medical travel support needed for this patient? ☐ Yes ☐ No

The RETHYMIC Connect™ Commercial Co-Pay Program could provide assistance for out-of-pocket costs for RETHYMIC.

Is commercial co-pay support needed for this patient? ☐ Yes ☐ No

## PROVIDER INFORMATION

Provider Name: _____ Tax ID #: _____ NPI #: _____

Institution/Facility Name: _____

Street Address: _____ City: _____ State: _____ Zip: _____

Provider Email: _____ Office Contact Name: _____

Office Contact Phone #: _____ Fax #: _____

Office Contact Email: _____

☐ Please check this box and provide your email address if you would like us to send an electronic version that you can sign.

Email: _____

**Provider Signature:** _____ **Date:** _____

**If you are a parent/caregiver/legal guardian, please fill out the consent release on page 2.** →

# Authorization to Use and Disclose Personal Health Information

To be completed by parent/caregiver/legal guardian

In signing this form, I authorize the patient's healthcare providers, and any vendors to provide Sumitomo Pharma America, Inc., its affiliates, parent company, business partners, service providers, third-party contractors, and agents (collectively "Sumitomo Pharma America, Inc.") with any and all names, addresses, patients' conditions and diagnoses, health insurance information, and demographic information (Personal Health Information or PHI) that Sumitomo Pharma America, Inc. requests for the purposes of providing patient support services to the patient and family members. Sumitomo Pharma America, Inc. may also contact me or the patient's providers directly for any missing or additional information.

I authorize Sumitomo Pharma America, Inc. to use PHI for purposes including the sharing of information with the child's healthcare providers or site of administration and to provide me with educational materials, logistical support such as facilitating travel and lodging where applicable, and marketing information via telephone or mail, or electronic format or otherwise for information that may be of interest to me and understand that my wireless service provider's message and data rates may apply. I authorize Sumitomo Pharma America, Inc. to perform reimbursement support and agree that a benefits investigation to determine coverage for treatment, identify other ways to afford treatment, to share information with my child's healthcare provider or site of administration, and understand that RETHYMIC Connect, and its authorized third-party agents may use my and my child's information to determine eligibility in the RETHYMIC Connect Co-Pay Assistance Program.

## Additional Terms of Consent Applicable to program offerings

**I understand this authorization is voluntary. If I decline to sign or provide verbal consent, I understand that Sumitomo Pharma America, Inc. may be limited in the support it would otherwise provide upon enrolling in the RETHYMIC Connect program, but my failure to sign this form will not otherwise affect the patient's current and ongoing medical care, their ability to participate in programs sponsored by Sumitomo Pharma America, Inc. in the future, or the patient's eligibility for healthcare benefits. RETHYMIC Connect and its authorized third-party agents reserve the right to ask for additional documents or information at any time.**

**I understand that my signed consent to share and use my and the patient's PHI lasts for three (3) years from the date of my signature or verbal consent.**

**I understand that I may revoke this written or verbal Authorization at any time in writing by sending a letter to Sumitomo Pharma America, Inc. at the following address: Sumitomo Pharma America, Inc., 84 Waterford Dr, Marlborough, MA 01752. By revoking this Authorization, Sumitomo Pharma America, Inc. is prevented from further using or disclosing my or the patient's information but will not affect the use or disclosure of information that has already been made in reliance on this Authorization, and understand I have a right to receive a copy of this form. I understand upon disclosure of this information, federal and state privacy laws may no longer apply or protect the information from further disclosure.**

**Unless I expressly revoke this Authorization, it shall remain in effect for ten (10) years from the date that I sign below or provide verbal consent.**

## Consent Information

I have read and understand the Authorization to Use and Disclose Personal Health Information and hereby provide consent.

☐ Please check this box and provide your email address if you would like us to send an electronic version that you can sign.

Email: _____

**Name (Print):** _____

**Signature:** _____

**Relationship to Patient:** _____ **Date:** _____

**Please note: Verbal attestation can be provided by the parent/caregiver/legal guardian if they are unable to sign the form by calling RETHYMIC Connect toll-free at 877-RETHYMC (877-738-4962), Monday–Friday, 8:00 AM to 8:00 PM ET.**

## 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.

**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 see full Prescribing Information at RETHYMIC.com**

**RETHYMIC Connect**
PO Box 220701, Charlotte, NC 28222
Fax: 888-936-8859 • Phone: 877-RETHYMC (877-738-4962)

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