Patient Enrollment Form

RETHYMIC®
allogeneic processed thymus tissue-agdc

Parent or Guardian: Complete Steps 1 and 2 and sign consent on page 2.

Physician: Complete Steps 3 and 4 and fax completed form to Enzyvant CONNECT at 888-936-8859.

For assistance, call Enzyvant CONNECT toll-free at 844-ENZCNCT (844-369-2628), Monday through Friday, 8:00 AM to 8:00 PM ET.

This form is intended for US patients only.

STEP 1: PATIENT/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: _____

Home Phone #: _____ Cell Phone #: _____

Email: _____

Best time to contact: ☐ AM ☐ PM Can we leave a message? ☐ Yes ☐ No

STEP 2: INSURANCE INFORMATION OF RESPONSIBLE PARTY (Required if patient Benefits Verification is requested.)

Primary Insurance: _____ Secondary Insurance: _____

Policy Holder Name: _____ Policy Holder Name: _____

Policy ID#: _____ Policy ID#: _____

Group #: _____ Group #: _____

Phone #: _____ Phone #: _____

STEPS 3 & 4 TO BE COMPLETED BY PRESCRIBER

STEP 3: PRESCRIBER INFORMATION

Prescriber Name: _____ Tax ID #: _____ NPI #: _____

Institution/Facility Name: _____

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

Prescriber Email: _____

Office Contact Name: _____

Office Contact Phone #: _____ Fax #: _____

Office Contact Email: _____

STEP 4: RETHYMIC PRESCRIPTION INFORMATION

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

Patient Allergies: _____ ☐ No known allergies

Body Surface Area (BSA): _____ Date BSA Taken: _____

The recommended dose range is 5,000 to 22,000 mm^2 of RETHYMIC surface area/m^2 recipient BSA

Quantity: 1 – No Refills

RETHYMIC is surgically implanted at Duke Health, 2301 Erwin Rd., Durham, NC 27710.

Is air travel needed for patient? ☐ Yes ☐ No

☐ I certify that I have made an independent judgment that RETHYMIC is necessary for the treatment of congenital athymia for the patient listed above. The information provided is accurate to the best of my knowledge. I will comply with state-specific prescription requirements. I authorize Enzyvant CONNECT to transmit this prescription to the appropriate facility.

Prescriber Signature _____

Dispense as Written (No Stamp Permitted) Date: _____

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 other vendors to provide Enzyvant Therapeutics, GmbH, its affiliates, parent company, business partners, service providers, third-party contractors, and agents (collectively "Enzyvant") with any and all name, address, patient's condition and diagnoses, and demographic information and agents (collectively Enzyvant) with any and all name, address, patient's condition and diagnoses, health insurance information, and demographic information (Personal Health Information or PHI) that Enzyvant requests for the purposes of providing patient support services to the patient and family members. Enzyvant may also contact me or the patient's healthcare providers directly for any missing or additional information.

I authorize Enzyvant to use PHI for the following purposes:

- To contact me via telephone or mail, in electronic format or otherwise, to provide or offer information that it believes to be of interest to me
- To provide logistical support such as facilitating travel and lodging (where applicable) for the provision of services and products
- To help Enzyvant develop programs and services that may be of interest to me
- To provide me with educational or marketing information
- For Enzyvant's internal business purposes and analytics, including to analyze its patient population and evaluate and improve the patient support program
- To conduct a benefits investigation to determine coverage for treatment
- To help you find other ways to afford treatment
- To share information with your healthcare provider

I understand that Enzyvant CONNECT and its authorized third-party agents may use my information to decide if I qualify to participate in the Enzyvant CONNECT Copay Assistance Program. My date of birth and/or additional demographic information as needed may be used to access my credit information and information derived from public and other sources to estimate my income in conjunction with the eligibility determination process for the Enzyvant CONNECT Copay Assistance program. As a soft credit inquiry, this option will not impact my credit score. Enzyvant CONNECT and its authorized third-party agents reserve the right to ask for additional documents and information at any time.

I understand that this Authorization is voluntary. If I decline to sign, I understand that Enzyvant may be limited in the services that it would otherwise provide under its Enzyvant CONNECT program, but my failure to sign this form will not otherwise affect the patient's current and ongoing medical care, the patient's ability to participate in Enzyvant-sponsored programs in the future, or the patient's eligibility for healthcare benefits.

Your signed permission to share and use your PHI lasts for one year from the date of your signature.

I understand that I may revoke this Authorization at any time in writing by sending a letter to Enzyvant at the following address: Enzyvant CONNECT, 55 Cambridge Parkway, Suite 102W, Cambridge, MA 02142. Revoking this Authorization will prevent Enzyvant from further using or disclosing my or the patient's information but will not affect use or disclosure of information that has already been made in reliance on this Authorization. You have the right to receive a copy of this form.

I understand that once the information has been disclosed, 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 five (5) years from the date that I sign below. If I need to request a copy of the Authorization for my records in writing, I will refer to the aforementioned address.

I agree to be contacted by Enzyvant via mail, email, and telephone calls and at the address(es) I have provided on this form for all marketing and non-marketing purposes described in this Authorization. I confirm I am the subscriber for the telephone number(s) provided and authorized user for the email address(es) provided. I understand that my wireless service provider's message and data rates may apply.

Consent Information

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

Name (Print) _____

Signature _____

Relationship to Patient_____ Date _____

Please note: If parent/caregiver/legal guardian is unable to sign the form, verbal attestation can be provided by calling Enzyvant CONNECT toll-free at 844-ENZCNCT (844-369-2628), Monday through Friday, 8:00 AM to 8:00 PM ET.

Indication and Important Safety Information

Indication

RETHYMIC® (allogeneic processed thymus tissue–agdc) 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 is unlikely to develop prior to 6-12 months after treatment with RETHYMIC. Immune reconstitution is needed for the body to produce cells in the immune system to fight infection. Your child's doctor should advise you of infection control measures which should be followed immediately after treatment and until the immune system starts working at a sufficient level. Monitor your child closely for signs of infection, including fever. Your child should be maintained on immunoglobulin replacement and prophylactic antimicrobials until certain criteria are met as determined by your 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, enlarged lymph nodes, inflammation of the gastrointestinal system and/or diarrhea.

Autoimmune Disorders: Autoimmune-related adverse events occurred in patients treated with RETHYMIC. These events included: low platelets, low white blood cells, protein in urine, low red blood cells, hair loss, poor thyroid function, inflammation of liver, inflammation of the joints, inflammation of the 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 including performing blood tests.

Kidney Disease: Treatment with RETHYMIC is a risk factor for death in patients with pre-existing kidney disease.

Cytomegalovirus (CMV) Infection: In clinical studies with RETHYMIC, 3 out of 4 patients with pre-existing CMV infection prior to the implantation with RETHYMIC died. Talk to your doctor about the benefits/risks of treatment if your child has pre-existing CMV infection.

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

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

Vaccinations: Your child should not receive any vaccinations until he or she has met certain requirements set by your doctor. Talk to your child's doctor prior to any vaccinations.

Anti-HLA Antibodies: Prior to 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, he/she will need to receive RETHYMIC from a donor that does not express those HLA proteins.

Indication and Important Safety Information (cont.)

HLA Typing: If your child has received a hematopoietic cell transplantation (HCT) or a solid organ transplant, they will have a test to look for specific antibodies that could interfere with the effect of RETHYMIC. If they are present, then it will be necessary to receive RETHYMIC from a certain group of donors that do not have these proteins.

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

What are the most common side effects with RETHYMIC?

The most common side effects with RETHYMIC are hypertension (high blood pressure), cytokine release syndrome, rash, hypomagnesemia (low magnesium), renal impairment / failure (decrease of kidney function), thrombocytopenia (low platelets), and graft versus host disease.

These are not all of 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 Product Information at RETHYMIC.com.

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