mymesoblast

Enrollment Form for Ryoncil® (remestemcel-L-rknd)

Please complete and fax this form to **833-637-6008**. For assistance call **833-637-6007**, 8AM - 8PM EST

WWW.RYONCIL.COM MAILING ADDRESS: MYMESOBLAST, PO BOX 220733, CHARLOTTE, NC 28222

MyMesoblast provides copay support or free medication, through our Patient Assistance Program, to patients who meet specific program eligibility requirements. To begin the evaluation process for this program, please complete, sign and submit this form as outlined below. To prevent processing delays all fields of this application must be completed.

1. PATIENT INFORMATION (*REQUIRED FIELD)

Patient First Name*: _____ MI: _____ Patient Last Name*: _____

Date of Birth (MM/DD/YYYY)*: _____ / _____ / _____ Primary Phone: (_____) _____ - _____ Alternate Phone: (_____) _____ - _____

Street Address*: _____

City*: _____ State*: _____ ZIP Code*: _____

Alternate Contact/Legal Guardian Information:

First Name*: _____ Last Name*: _____

Relationship of Alternate Contact/Legal Guardian to Patient: _____

Email: _____ Primary Phone: (_____) _____ - _____ Alternate Phone: (_____) _____ - _____

Preferred Language: ❒ English ❒ Spanish ❒ Other _____

PATIENT CONSENT AND AUTHORIZATION

I (patient's legal guardian) consent to MyMesoblast communicating directly with me on the patient's behalf. ❒ Yes ❒ No

I have read and agree to the Patient Authorization on page 4. By signing, I understand that MyMesoblast may contact me regarding educational or other support programs as described in the Patient Authorization.

Legal Guardian Signature*: _____ Date (MM/DD/YYYY)*: _____ / _____ / _____

(Refer to page 4): If I am signing this authorization on behalf of the individual named on this form as their personal representative, my authority to act on the patient's behalf is the following:

(e.g., health care power of attorney, legal guardian) _____

2. PATIENT INSURANCE & FINANCIAL INFORMATION (*REQUIRED FIELD)

(A copy of the front and back of the patient's insurance card(s) can be attached in lieu of completing this section.)

❒ Patient Has No Insurance	PRIMARY INSURANCE	SECONDARY INSURANCE
Insurance Name*		
Policy Holder Name		
Policy Holder's Date of Birth		
Relationship to Patient		
Beneficiary ID/Policy #*		
Group #*		
Insurance Phone #		

The following information is required only for the Patient Assistance Program, which provides free product to patients who meet specific eligibility criteria. To assess your eligibility for this program please provide the following income information, social security number, and consent. MyMesoblast reserves the right to request proof of income to validate patient's eligibility for the Patient Assistance Program.

Annual Gross Household Income (Before Taxes): $ _____ # Living in Household: _____

Social Security Number of Patient or Legal Guardian: _____

PATIENT CERTIFICATION

I authorize MyMesoblast and their agents to use my Social Security Number, demographic information, and other information provided to obtain and assess my credit report and information derived from public record and other sources to estimate my income in conjunction with the eligibility determination process, including Real Time Income Projections (RTIPs).

Legal Guardian Signature*: _____ Date (MM/DD/YYYY)*: _____ / _____ / _____

(Refer to page 4): If I am signing this certification on behalf of the individual named on this form as their personal representative, my authority to act on the patient's behalf is the following:

(e.g., health care power of attorney, guardian) _____

Please see Indication and Important Safety Information on page 4. **Click here** for Full Prescribing Information.

Continue on next page ▶

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3. PRESCRIBER AND FACILITY CONTACT INFORMATION (*REQUIRED FIELD)

Prescriber Name (Last, First)*: _____ Prescriber Specialty: _____

NPI #*: _____ State License #: _____ Medicaid Provider # (Required if Medicaid Patient): _____

Facility Name*: _____ Facility Type: ❒ Hospital Outpatient ❒ Hospital Inpatient ❒ Other _____

Street Address*: _____ City*: _____ State*: _____ ZIP Code*: _____

Email: _____ Phone*: (_____) _____ - _____ Fax*: (_____) _____ - _____

Primary Office/Facility Contact*: _____ Title/Role: _____ Phone*: (_____) _____ - _____ Fax*: (___) _____ - _____

Email: _____

Primary Cell Lab/Delivery Contact*: _____ Title/Role: _____ Phone*: (_____) _____ - _____ Fax*: (___) _____ - _____

Street Address*: _____ City*: _____ State*: _____ ZIP Code*: _____

4. PRESCRIPTION AND CLINICAL INFORMATION FOR RYONCIL® (*REQUIRED FIELD)

Patient First Name*: _____ Patient Last Name*: _____ Date of Birth (MM/DD/YYYY)*: ____ / ____ / _____

Primary Diagnosis ICD-10-CM Code*: ❒ D89.810 – Acute Graft-Versus-Host Disease ❒ D89.812 – Acute or Chronic Graft-Versus-Host Disease ❒ Other ICD-10-CM Diagnosis Code:_____

Has the Patient Started Treatment? ❒ New to RYONCIL® ❒ Continuing on RYONCIL® Due to Partial or Mixed Response ❒ Recurrence of GvHD After Complete Response to RYONCIL®

Treatment Start Date (MM/DD/YYYY): _____ / _____ / _____ Doses per Week: _____

Total # of Infusions in Treatment Plan: _____ Number of Prior RYONCIL® Infusions : _____ ❒ Unknown

Have You Previously Received Steroid Treatment*: ❒ No ❒ Yes Previous Treatments: _____

Drug Allergies*: ❒ No ❒ Yes (If Yes, Please List Medication(s) and Reaction(s)):_____

Patient Weight: _____ ❒ lb. ❒ kg. Site of Care: ❒ Hospital Outpatient ❒ Hospital Inpatient Infusion Center ❒ Other (e.g., Physician Office, Home Infusion) _____

Kit Number*	Patient Weight (Kg)	Number of Vials in Each Kit	Number of Kits Needed For:		
			Initial Course	Repeat Administration	Recurrence of GvHD After Complete Response
❒ Kit 1	<12.5	1 Vial	8	4	8
❒ Kit 2	12.5-<25	2 Vials			
❒ Kit 3	25-<37.5	3 Vials			
❒ Kit 4	37.5-<50	4 Vials			
❒ Kit 5	50-<62.5	5 Vials			
❒ Kit 6	62.5-<75	6 Vials			
❒ Kit 7	75-<87.5	7 Vials			
❒ Kit 8	87.5-<100	8 Vials			

Indication: RYONCIL is indicated for the treatment of steroid refractory acute graft versus host disease (SR-aGvHD) in pediatric patients 2 months of age and older.

Important Safety Information: Contraindications: Do not use RYONCIL in patients with known hypersensitivity to dimethyl sulfoxide (DMSO) orporcine and bovine proteins.

PRESCRIBER CERTIFICATION

I certify that the above therapy is medically necessary, and that the information provided is current, complete, and accurate to the best of my knowledge. I certify that I am the physician who has prescribed the Mesoblast product to the previously identified patient, and that I provided the patient with a description of MyMesoblast. I understand that completing this enrollment form does not guarantee that assistance will be provided to my patient. I have received authorization to release the information above and other protected health information (as defined by HIPAA) to MyMesoblast. I will not seek reimbursement for free product provided to the patient. I certify that the product provided through MyMesoblast is intended solely for the patient identified on this form and will be used only by the enrolled patient. I will notify MyMesoblast immediately if the Mesoblast product is no longer medically necessary for this patient's treatment or if my patient's insurance or financial status changes. I understand that Mesoblast reserves the right to modify or discontinue the program at any time and to verify the accuracy of the information submitted.

Print Name: _____

Signature*: _____ Date (MM/DD/YYYY)*: ____ / ____ / _____

To ensure compliance with MyMesoblast, the legal guardian must sign the patient certification and authorization on page 1, while the prescriber must sign the prescriber certification on this page. All signatures must be dated, legible, and completed before submission to avoid processing delays.

Please see Indication and Important Safety Information on page 4. **Click here** for Full Prescribing Information.

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5. PATIENT CONSENT

Please read the following carefully, then sign and date where indicated on page 1.

PATIENT AUTHORIZATION

By completing this application you are providing authorization to Mesoblast and its agents engaged in providing services under MyMesoblast (collectively, "Mesoblast") for the collection of certain information that is necessary in order to evaluate your enrollment into MyMesoblast, and if enrolled, to provide you with the product at no cost to you. This personal information may be shared with physicians and health insurers in order to provide you with program services, including

i. verifying or coordinating insurance coverage or otherwise obtain payment for my treatment with the product selected by my HCP,

ii. coordinating my receipt of and payment of the product selected by my HCP, and/or

iii. facilitating my access to the product selected by my HCP.

By completing this application, you are agreeing that the information you provide is accurate and you have made no misrepresentations regarding your residency, insurance status, or income. You are required to notify the program of insurance changes or financial changes that may impact your eligibility for the program. You will promptly provide to MyMesoblast all documentation and information requested by the program to verify the accuracy of your eligibility, including any and all documentation requested by MyMesoblast pertaining to your income level, financial situation, insurance status and medical condition. MyMesoblast may terminate your enrollment in the program if you fail to comply with our request for any documentation.

I understand that MyMesoblast and its agents will request only that information needed to process and administer this application, and that they will not disclose the information they obtain, except as needed for this purpose or as required by applicable law and, if approved, to administer my participation in the program.

I hereby represent, covenant and certify as follows: **(a)** the medical and insurance information in this form is provided with my consent; **(b)** the information contained in this application is complete and accurate to the best of my knowledge; **(c)** I understand that if my prescription drug plan coverage changes or if my financial status changes, I may no longer be eligible under this program, and I will promptly notify MyMesoblast of any such changes; **(d)** in the event that I become eligible for a benefit through a federal, state or private program which may reimburse for the medication requested I will notify MyMesoblast and understand that I may no longer be eligible for assistance; **(e)** upon the request of MyMesoblast and/or its agents/representatives, I will provide documentation—including but not limited to personal financial records—to verify the information contained in this application; **(f)** I understand that if there is a determination at any time that I am no longer eligible for this program, Mesoblast may immediately stop any assistance provided under this program; and **(g)** I will notify MyMesoblast of any errors regarding the foregoing and will make every effort to correct those errors.

I authorize my healthcare providers and staff (together, "Healthcare Providers"), health insurer, health plan or programs that provide healthcare benefits (together, "Health Insurers") to disclose to Mesoblast and its agents ("Mesoblast") health information about me, including information related to my medical condition and treatment, health insurance coverage and claims, and prescription (including fill/refill information) related to their prescription for RYONCIL® (remestemcel-L) therapy ("Patient Information"). I understand the disclosure to Mesoblast will be for the purposes of enrolling in, and providing certain services through the "MyMesoblast," including:

- to determine eligibility to participate in MyMesoblast coverage assistance programs, patient assistance programs, or other support programs
- to investigate health insurance coverage for RYONCIL®
- to obtain prior authorization for coverage
- to assist with appeals of denied claims for coverage
- for the operation and administration of MyMesoblast, including communicating with me about the program
- to refer me to, or to determine my eligibility for, other programs, or alternative sources of funding or coverage that may be available to provide assistance with the costs of therapy
  - I understand that Mesoblast may de-identify Patient Information and use and disclose that deidentified information in performing research, education, business analytics, marketing studies, or for other commercial purposes, including linkage with other de-identified information Mesoblast receives from other sources.
  - I understand and agree that Mesoblast may use Patient Information for these purposes and may share it with the my Healthcare Providers, Health Insurers and Specialty Pharmacies.

Once Patient Information has been disclosed to Mesoblast, I understand that federal privacy laws may no longer protect it from further disclosure. However, I also understand Mesoblast has agreed to protect the Patient Information by using and disclosing it only for the purposes allowed by me in this Authorization or as otherwise required by law. I understand that I do not have to sign this Authorization. A decision by me not to sign this Authorization will not affect my ability to obtain medical treatment, payment for treatment, insurance coverage, access to health benefits or Mesoblast medications from covered entities such as Health Care Providers, Health Insurers, and Specialty Pharmacies. However, if I do not sign this Authorization, I understand that I will not be able to participate in MyMesoblast. I understand that this Authorization expires 24 months from the date support is last provided under the program, unless and until I withdraw (take back) this Authorization before then, or as otherwise required by law. Further, I understand that I may withdraw this Authorization at any time by mailing or faxing a written request to MyMesoblast at PO Box 220733, Charlotte, NC 28222; Fax: 1-833-637-6008. Withdrawal of this Authorization will end my participation in MyMesoblast and will not affect any disclosure of the Patient Information based on this Authorization made before my request is received and processed by my Healthcare Providers, Health Insurers, and Specialty Pharmacies. I understand that I may request a copy of this Authorization.

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Please see Indication and Important Safety Information on page 4. **Click here** for Full Prescribing Information.

6. INDICATION AND IMPORTANT SAFETY INFORMATION

INDICATIONS AND USAGE

RYONCIL is indicated for the treatment of steroid refractory acute graft versus host disease (SR-aGvHD) in pediatric patients 2 months of age and older.

IMPORTANT SAFETY INFORMATION

Contraindications

Do not use RYONCIL in patients with known hypersensitivity to dimethyl sulfoxide (DMSO) or porcine and bovine proteins.

WARNINGS AND PRECAUTIONS

Hypersensitivity and Acute Infusion Reactions

Hypersensitivity reactions including acute infusion reactions have occurred with RYONCIL administration. Serious hypersensitivity reactions, including anaphylaxis, may occur due to DMSO and trace amounts of porcine or bovine proteins. Signs and symptoms may include fever, dyspnea, and hypotension during or after RYONCIL infusion.

Premedicate patients with antihistamine and corticosteroids and monitor closely for signs and symptoms of hypersensitivity or acute infusion reactions.

If a hypersensitivity or infusion reaction occurs, interrupt RYONCIL infusion. Do not administer RYONCIL in patients who experience serious or life-threatening reactions.

Transmission of Infectious Agents

Transmission of infectious disease or agents may occur with RYONCIL administration because it contains cells from human donors and is manufactured using human, porcine and bovine-derived reagents. Donors are screened and tested for Human Immune-deficiency Virus 1 (HIV-1); Human Immune-deficiency Virus 2 (HIV-2); Hepatitis B Virus (HBV); Hepatitis C Virus (HCV); Human T-cell Leukemia-lymphoma Virus 1 (HTLV-1); Human T-cell Leukemia-lymphoma Virus 2 (HTLV-2); West Nile Virus (WNV); Cytomegalovirus (CMV); Epstein-Barr Virus (EBV); and Syphilis (Treponema pallidum). Screening was performed for Creutzfeldt-Jakob disease (CJD) and communicable disease risks associated with xenotransplantation. RYONCIL cell banks are tested for human and animal viruses, retroviruses, bacteria, fungi, yeast, and mycoplasma. Human and animal-derived reagents are tested for human and animal viruses, bacteria, fungi, and mycoplasma before use. These measures do not eliminate the risk of transmitting these or other infectious diseases or agents.

Ectopic Tissue Formation

Ectopic tissue formation may occur following treatment with RYONCIL due to the ability of human mesenchymal stromal cells to differentiate into mesenchymal lineage cells such as bone, cartilage and fat cells.

ADVERSE REACTIONS

Clinical Trials Experience

Because clinical studies are conducted under widely varying conditions, adverse reaction rates observed in the clinical studies of a drug cannot be directly compared to rates in the clinical studies of another drug and may not reflect the rates observed in practice.

The safety data described in this section reflect exposure to RYONCIL in 54 patients in Study MSB-GVHD001 for the treatment of SR-aGvHD. Patients received intravenous infusion of RYONCIL at a dosage of 2 x 106 MSCs/kg twice a week for four consecutive weeks, for a total of eight infusions. Patients with partial or mixed response at Day 28 received additional infusions of RYONCIL 2 x 106 MSCs/kg once a week for an additional four weeks. The median number of doses administered were 10 (range 1 to 16), and the treatment was administered over a median of 43 days (range 1 to 104 days).

Serious adverse reactions occurred in 35 patients (65%) including pyrexia (n=5;9%), respiratory failure (n=5;9%), pneumatosis intestinalis (n=4;7%) and staphylococcal bacteremia (n=2;<5%). Eight patients had discontinuation of RYONCIL treatment due to the following: acute infusion reactions (n=3), hypotension (n=1), gastroenteritis (n=1), and death (n=3).

Adverse reactions ≤ grade 3 occurring in ≥10% of patients in Study MSB-GVHD001 up to day 100 after RYONCIL treatment included viral infectious disorders, bacterial infectious disorders, infections – pathogen unspecified, pyrexia, hemorrhage, abdominal pain, hypertension, vomiting, arrhythmia, diarrhea, rash, arthralgia, fungal infectious disorders, hypotension, cough and respiratory failure. No grade 4 or 5 adverse reactions occurred in the study.

Grade 3 or 4 laboratory abnormalities that worsened from baseline in ≥ 10% of patients in Study MSB-GVHD001 included elevated Gamma-glutamyl transferase, thrombocytopenia, and elevated bilirubin.

USE IN SPECIFIC POPULATIONS

Pregnancy

There are no available data for RYONCIL use in pregnant women. No animal reproductive and developmental toxicity studies have been conducted with RYONCIL to assess whether it can cause fetal harm when administered to a pregnant woman. It is not known if RYONCIL has the potential to be transferred to the fetus. Therefore, RYONCIL is not recommended for women who are pregnant. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2-4% and 10-20%, respectively.

Lactation

There is no information regarding the presence of RYONCIL in human milk, the effect on the breastfed infant, and the effects on milk production. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for RYONCIL and any potential adverse effects on the breastfed infant from RYONCIL or from the underlying maternal condition.

You may report side effects to the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch. You may also report side effects to Mesoblast at toll-free phone #1-844-889-MESO (6376)

Please see the RYONCIL Full Prescribing Information for additional Important Safety Information.