

Trethera Expanded Access Request Form

For Use by Treating Physicians Only

Section 1: Physician Contact Information

Physician Name: _____

Medical License Number & State: _____

Institution / Practice Name: _____

Specialty: _____

Phone Number: _____

Email Address: _____

Section 2: Patient Clinical Information (Do not include full name or PHI)

Diagnosis (Include ICD-10 code if available):

Brief Summary of Medical History & Prior Treatments:

Performance Status (e.g., ECOG/Karnofsky): _____

Is the patient currently eligible for any ongoing clinical trial involving this agent?

☐ Yes ☐ No (If No, briefly explain why)

Section 3: Treatment Plan

Requested Investigational Product:

☐ TRE-515 ☐ Other: _____

Proposed Dose and Administration Schedule:

Planned Duration of Treatment:

Planned Concomitant Medications:

Section 4: Oversight & Compliance

Institutional Review Board (IRB) Name:

IRB Contact Email / Phone:

Has IRB approval been obtained?

☐Yes ☐No ☐Pending

Will the physician submit FDA Form 3926 to the FDA?

☐Yes ☐No

Section 5: Justification for Expanded Access

Please describe the rationale for this request and potential benefit to the patient:

Why are no alternative therapies suitable or available?

Section 6: Acknowledgment

I confirm that:

- I am a US licensed physician responsible for this patient's care.
- I understand that TRE515 is an investigational agent.
- I will ensure appropriate informed consent is obtained from the patient.
- I will comply with FDA and IRB requirements before initiating treatment.

Physician Signature: _____

Date: _____

Submit Completed Form To:

Trethera Expanded Access Team

✉ Email: info515@trethera.com