



## Expanded Access Request Form

For Use by Treating Physicians Only

### Section 1: Physician Contact Information

Physician Name

Medical License Number & State

Specialty

Institution / Practice Name

Phone Number

Email Address

### Section 2: Patient Clinical Information

*Do not include full name or PHI.*

Diagnosis

Brief Summary of Medical History & Prior Treatments

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

Is 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

Planned Concomitant Medications

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 TRE-515 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](mailto:info515@trethera.com)