



U.S. FOOD & DRUG
ADMINISTRATION

Memorandum

DATE: March 5, 2025

TO: Crystal Melendez, MT, RN, BSN, RPM, CBER/OTAT/DRPM
Carolina Panico, M.D., Ph.D., Committee Chair, CBER/OTAT/DCGT
Ekaterini Tsilou, M.D., Clinical Reviewer, CBER/OTAT/DCEPT

FROM: Benjamin S. Cyge, Ph.D.
Consumer Safety Officer
APLB/DCM/OCBQ

THROUGH: Lisa L. Stockbridge, Ph.D.
Branch Chief
APLB/DCM/OCBQ

SUBJECT: ENCELTO (revakinagene taroretcel-lwey)
BLA: 125798/0
Sponsor: Neurotech Pharmaceuticals, Inc.

Background

The sponsor submitted:

☒ New Approval
☐ Changes Being Effectuated (CBE) supplement
☐ Prior Approval Supplement (PAS)
☐ Major Amendment

Submission contains:

☒ Prescribing Information (PI)
☐ Patient Package Insert (PPI)
☐ Package and/or container labels
☐ Other

Submission Date: April 18, 2024

PDUFA Action Date: December 17, 2024

APLB Comments/Recommendations

On April 18, 2024, Neurotech Pharmaceuticals submitted their Biologics License Application (BLA 125798) for ENCELTO. ENCELTO is an allogeneic encapsulated cell-based gene therapy product indicated for the treatment of adults with idiopathic macular telangiectasia type 2 (MacTel).

The ENCELTO Review Team iteratively negotiated revisions to the Prescribing Information (PI) through communications with the applicant. APLB has reviewed the revised PI, dated March 3, 2025 and found it acceptable from a promotional and comprehension perspective.

If you have any questions regarding this review, please contact Benjamin S. Cyge, Consumer Safety Officer at (301) 796-4212.
