



First FDA-Approved Treatment for MacTel Performed

Cumberland, R.I., August 11, 2025 – Neurotech Pharmaceuticals, Inc., a private biotech company focused on developing transformative therapies for chronic eye diseases, announced the first commercial manufacturing, shipment, and surgical procedure for ENCELTO™ (revakinagene taroretcel-lwey), an encapsulated cell-based gene therapy and the first and only FDA-approved treatment for adults with idiopathic Macular Telangiectasia Type 2 (MacTel).

“This is a huge milestone for people living with MacTel. For the first time, there is an FDA-approved treatment option that could change what is possible for patients. We have been working toward this for years, and seeing it become a reality is incredibly exciting for the Neurotech team and most importantly, for the patients who may benefit,” said Richard Small, Chief Executive Officer.

“Performing the first ENCELTO surgery for a patient with MacTel outside of a clinical trial is an important milestone. For the first time, we can offer a valuable and durable treatment option for patients, one that slows their loss of photoreceptors and maintains more visual function over time,” said Charles C. Wykoff, MD, PhD, Retinal Consultants of Texas, Houston, TX. “Many patients with MacTel experience gradual and progressive functional declines over time, and it is exciting to be able to offer an option to change the course of their disease.”

About Macular Telangiectasia Type 2 (MacTel)

Macular Telangiectasia Type 2 (MacTel), or idiopathic macular telangiectasia type 2, is a bilateral, neurodegenerative disease in adults with characteristic localized retinal degeneration that causes the gradual loss of cells in the retina, resulting in vision loss and secondary alterations of the retinal vasculature, the network of blood vessels that supplies oxygen and nutrients to the retina.

About Encapsulated Cell Therapy (ECT)

ENCELTO is an encapsulated cell-based gene therapy designed to provide long-term, sustained delivery of therapeutic proteins for the treatment of chronic eye diseases. ENCELTO is the first technology to use Neurotech’s versatile ECT platform, consisting of a small, semi-permeable capsule containing the proprietary allogeneic retinal pigment epithelium (RPE) cells genetically engineered to produce specific therapeutic proteins for targeted disease treatment. The capsule is surgically inserted. Once in place, the capsule’s semi-permeable exterior membrane delivers the therapeutic proteins into the eye where they can travel to the retina located at the back of the eye. The exterior membrane protects the encapsulated RPE cells from the host’s immune system, contributing to their survival and functionality over time.

About Neurotech Pharmaceuticals, Inc.

Neurotech Pharmaceuticals, Inc. is a private biotech company focused on developing transformative therapies for chronic eye diseases. The core platform technology, Encapsulated Cell Therapy (ECT), is a first-in-class drug delivery platform designed to slow the progression of Macular Telangiectasia Type 2 (MacTel) and other chronic eye diseases. ENCELTO™ (revakinagene taroretcel-lwey) is approved in the United States for the treatment of adults with idiopathic Macular Telangiectasia Type 2 (MacTel).



About ENCELTO™

ENCELTO is an encapsulated cell-based gene therapy. It is a small capsule, about the size of a grain of rice, that is placed inside the eye to release a protein called recombinant human ciliary neurotrophic factor (rhCNTF) that can directly reach the retina, the light sensitive part of the eye. The capsule contains living cells that have been genetically modified to continuously produce and release rhCNTF. This protein helps protect certain cells in the retina, supporting their health and reducing the loss of light-sensing cells known as photoreceptors.

ENCELTO is used to treat adults with idiopathic Macular Telangiectasia Type 2 (MacTel); a retinal disease that causes progressive vision loss. Your eye surgeon will assess your vision and review your medical history to determine if ENCELTO is the right treatment for you.

IMPORTANT SAFETY INFORMATION

Who should not receive an ENCELTO surgical implant?

ENCELTO has not been tested in pediatric patients or pregnant women.

The outpatient surgical procedure should not be performed if you are currently experiencing an active or suspected eye infection.

You should not receive ENCELTO if you have a known hypersensitivity to Endothelial Serum Free Media (Endo-SFM).

Before receiving ENCELTO, tell your eye surgeon about all your medical conditions, including:

- Are pregnant or plan to become pregnant. Although studies have shown that rhCNTF does not enter the bloodstream, its effects on an unborn baby have not been fully studied.
- Are breastfeeding or plan to breastfeed. It is not known if rhCNTF passes into your breast milk.
- Any current infections.
- Are currently taking or have recently taken medicines that lower the chance of blood clots forming in the body such as warfarin, low or regular doses of aspirin, or nonsteroidal anti-inflammatory drugs (NSAID).

How is ENCELTO administered?

ENCELTO is inserted into the eye as an outpatient surgical procedure performed by an eye surgeon experienced in vitreoretinal surgery. If removal of ENCELTO is necessary, the removal surgery must also be done by an eye surgeon experienced in vitreoretinal surgery in an operating room as an outpatient surgery.

What should I avoid while taking ENCELTO?

Immediately post-operative:

- Avoid heavy lifting (over 20 pounds) for one week.
- Keep water out of the eye (e.g., close your eye while showering) for one week.
- Protect your eyes by wearing glasses or protective eyewear during the day and using an eye shield at night for one week.
- Do not drive or use machinery until the eye shield has been removed and your eye surgeon informs you that your vision has recovered to an acceptable level.

Post-operative care:

- Use a topical antibiotic solution at a frequency of 1 drop four times a day for 7 days.

- Use a steroid drop taper of prednisolone acetate 1% (or equivalent) starting the day after surgery with the following taper:
 - 1 drop four times a day for the first 7 days;
 - 1 drop three times a day for the next 7 days;
 - 1 drop two times a day for the next 7 days;
 - 1 drop once a day for the last 7 days.

Magnetic Resonance (MR) Conditional Information

IMPORTANT: ENCELTO is MR Conditional

You will receive an implant card, which should be shown to your imaging technician if you need Magnetic Resonance Imaging (MRI) at any time while the ENCELTO implant is in your eye. The card will include details about the ENCELTO implant, the date of insertion, and on the back, instructions for the imaging technician to access important MRI safety information.

What are the possible side effects of ENCELTO?

Please follow all post-operative instructions given by your eye surgeon and ensure you attend all follow-up visits as recommended.

Potential side effects:

Please be advised that ENCELTO and the surgical insertion has related risks such as, but not limited to, endophthalmitis (eye infection), retinal tear and detachment (retina tears and potentially separates from the eye wall resulting in vision loss), vitreous hemorrhage (bleeding within the central cavity of the eye), implant extrusion (the ENCELTO begins to work its way out of the way), suture related issues (such as suture related eye irritation or exposure of sutures), temporary or permanent loss of vision, accelerated cataract formation (clouding of the lens of the eye), and delayed dark adaptation (the ability of the eye to adjust from bright lighting conditions to dark lighting conditions).

If delayed dark adaptation occurs, it is unknown for how long these symptoms will be experienced. Take the following safety precautions:

- Driving: Delayed dark adaptation may impair one's ability to see objects, pedestrians, or road sign signs when moving rapidly from a brightly lit environment to a dimly lit environment (for example, entering a tunnel during the daytime).
- Navigating in the Dark: Take caution when moving from bright to dark areas, such as entering a dark room or stepping outside at dusk. Consider using flashlights, nightlights, or motion-activated lighting at home.
- Consider wearing sunglasses or tinted lenses in bright environments to reduce the impact of transitioning from light to dark.

It is common to experience the following symptoms following ENCELTO surgery:

- Sensation of something in the eye (i.e., foreign body sensation)
- Eye redness
- Eye irritation
- Eye dryness
- Eye discharge
- Mild to moderate eye pain or discomfort
- Floaters (small spots or shapes that appear in your vision)
- Headache

**When to Seek Eye Surgeon Advice**

You are to seek immediate care from an eye surgeon if there are sudden changes in your vision, such as an increase in floaters, the appearance of “spider webs,” flashing lights, sensitivity to light, loss of vision or visual field, progressively worsening eye pain, or increasing discharge/drainage from the eye as these symptoms could be a sign of a more serious issue.

Call your eye surgeon for medical advice about side effects. You may report side effects to the Food and Drug Administration (FDA) at 1-800-FDA-1088.

Please see full [Prescribing Information](#) and [Patient Information](#) for ENCELTO.

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