Enabled Therapeutics Gains FDA Alignment for CPT-021: A First-of-Its-Kind Targeted Therapy for Alzheimer's

Capton® Platform Paves the Way for Onsite Drug Synthesis That Could Revolutionize Neurology

SAN FRANCISCO, CA, UNITED STATES, March 24, 2025 /EINPresswire.com/ -- Enabled Therapeutics, a precision neurology company, today announced the successful completion of its U.S. Food and Drug Administration (FDA) pre-Investigational New Drug (Pre-IND) meeting for CPT-021, a first-in-class, neuroinflammation-targeted oral therapy for Alzheimer's disease. The FDA's feedback provides regulatory clarity, confirming that the studies required for IND submission align with Enabled Therapeutics' development plan. Successfully advanced, CPT-021 brings an affordable, disease-modifying Alzheimer's treatment to market within three to four years under Fast Track designation.

> The future of Alzheimer's treatment isn't about plaques—it's about precision"
>
> *Marcel Gradidge, CBO*
> *Enabled Therapeutics*

"This meeting was a critical milestone," said Sara Isbell, CEO of Enabled Therapeutics. "The FDA's response confirms our plan is on track with no hurdles. With funding, we can complete the necessary studies in 12 months and move CPT-021 into clinical trials—bringing much-needed innovation to Alzheimer's patients."

PATHOTARGETING: A BREAKTHROUGH IN ALZHEIMER'S THERAPY WITH CAPTONS

CPT-021 uses pathotargeting, a precision approach that ensures that drug activates only inside diseased brain regions. Unlike current therapies, which deliver active drug across the entire brain, CPT-021 circulates in a precursor form and completes its synthesis into homotaurine only where neuroinflammation is present.

Easily crossing the blood-brain barrier, CPT-021 targets areas of high oxidative stress (ROS), and metal ions, a hallmark of Alzheimer's, where it undergoes a natural chemical reaction to become active. This ensures high drug levels where needed while avoiding off-target toxicity.

Because this process is purely chemical, not biological, CPT-021 bypasses biological variability, making translation from lab to human trials highly predictable.

Homotaurine has shown the ability to reduce CNS inflammation by preventing immune cell invasion via the GABA system. However, previous clinical trials struggled to show efficacy—not because homotaurine is ineffective, but because systemic delivery limits dosing due to toxicity risks. Current approaches expose the entire brain to active drug, restricting how much can be given before side effects outweigh the benefits.

Revolutionizing Alzheimer's Treatment: Enabled Therapeutics' Capton® platform delivers precision-targeted drug activation inside inflamed brain regions, overcoming longstanding barriers in neurotherapeutics.

Captons solve this problem by ensuring that drug forms only where needed, allowing for higher drug levels at the disease site—without systemic toxicity. This breakthrough in drug design overcomes the challenges that have prevented effective CNS treatments from reaching the market. We expect to replicate preclinical success in human trials, a feat no other approach has achieved.

"For decades, CNS drugs have failed because they expose the entire brain to active drug, limiting efficacy before toxicity takes over," said Dr. Todd Zankel, Chief Scientific Officer of Enabled Therapeutics. "Captons change that. With pathotargeting, we're not just improving delivery—we're rewriting the rules of neurological drug design."

ADVANCING TOWARD CLINICAL TRIALS

With a clear regulatory path ahead, the FDA has outlined the next steps for CPT-021, including GLP toxicology studies and clinical trial planning—key milestones toward Fast Track designation. This reinforces confidence in CPT-021's rapid advancement into first-in-human trials.

Enabled Therapeutics, in collaboration with CRO and CDMO partners, has a 12-month plan to complete IND-enabling studies and manufacturing, with Phase I trial enrollment completion expected within 18 months—once funding is secured. If granted Fast Track designation, CPT-021

could reach patients within three to four years. Until then, Alzheimer’s patients continue to wait.

A BREAKTHROUGH FOR NEUROLOGY

Beyond Alzheimer’s, Capton® technology holds potential for treating other neurological conditions, including refractory epilepsy, traumatic brain injury (TBI), glioblastoma, and rare neurological diseases.

By leveraging thiol-based chemistry, the Capton® platform enables precise drug activation only in diseased brain tissue. This breakthrough in CNS drug development overcomes barriers that have long hindered neurological treatments—blood-brain barrier limitations, systemic toxicity, and unpredictable biological activation—offering a new level of safety and effectiveness. Alzheimer’s is just the beginning. By unlocking precision drug activation, Captons have the potential to reshape treatment for a wide range of neurological diseases.

About Enabled Therapeutics
Enabled Therapeutics is a clinical-stage pharmaceutical company developing pathotargeting, a thiol-based drug activation approach that selectively engages disease pathology while sparing healthy tissue. At the forefront of precision neurology, Enabled is advancing the Capton® platform to create oral, disease-modifying treatments for Alzheimer’s and other CNS disorders.

Forward-looking Statements
This press release contains forward-looking statements regarding the development and regulatory potential of CPT-021. Actual results may vary based on clinical trial outcomes, regulatory decisions, and other factors

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