



Embera NeuroTherapeutics Announces First Subject Dosed in Phase 2 Study of EMB-001 in Cocaine Use Disorder

-- Company to soon initiate second Phase 2 study of EMB-001 in Smoking Cessation --

-- Completed \$1.2M Series B Financing in June --

BOSTON, and SHREVEPORT, La. – August 31, 2020 - [Embera NeuroTherapeutics, Inc.](#), a specialty pharmaceutical company developing novel treatments for cocaine, nicotine and potentially other addictions, today announced that the first subjects have begun dosing of EMB-001 in a Phase 2 study for cocaine use disorder. EMB-001 is being tested to help patients struggling with addiction to maintain abstinence and improve their quality of life by simultaneously targeting multiple neurological pathways that play a role in stress-induced, cue-induced and drug-induced addiction relapse. Embera is developing the first medication that treats addiction by moderating activity in the stress response system.

The randomized, double-blind, placebo-controlled Phase 2 clinical trial is supported by funding from the National Institute on Drug Abuse (NIDA) of the National Institutes of Health and will evaluate EMB-001 as a treatment option for patients with cocaine use disorder. Eighty subjects will receive twice daily doses of EMB-001 or placebo for 13 weeks. The primary efficacy endpoint is abstinence in subjects dosed with EMB-001 versus placebo during the final three weeks of treatment.

“The Phase 2 study will evaluate the efficacy of EMB-001 in patients with cocaine use disorder,” said Bruce McCarthy, M.D., Chief Medical Officer of Embera. “EMB-001 was well-tolerated in the Phase 1b trial and we observed no serious adverse events when combining EMB-001 and cocaine, indicating that EMB-001 can be used safely in active cocaine users. The Phase 2 study will provide a significant opportunity to understand the potential of EMB-001 to help people struggling with cocaine addiction.”

In addition, Embera will begin a second Phase 2 clinical study evaluating EMB-001 as a potential smoking cessation therapy and expects first subjects to be dosed in the early fall. The study, with grant support from the Foundation for a Smoke-Free World, will be conducted at the Rose Research Center (RRC) in North Carolina.

In June 2020, Embera completed a \$1.2 million Series B financing with participation of current investors. Proceeds will support the company’s operations through completion of these two Phase 2 clinical studies.

“The initiation of the two Phase 2 clinical studies is a significant milestone for Embera as we investigate EMB-001’s effect in treating cocaine use disorder, for which there is currently no approved treatment available, and tobacco use disorder, for which current treatment options show limited long term

efficacy. We would like to thank our investors for their continued support as we work towards our goal of developing effective therapies for a broad range of addictions where there is a massive need,” said Gary Connor, RN, Chief Operating Officer of Embera. “Due to the impact of COVID-19, we have worked diligently to revise our safety protocols to minimize patients’ risk of exposure to the disease, including altering visit schedules and employing telehealth platforms for patients to be engaged from home.”

More information about Embera’s Phase 2 clinical trial is available at [Clinicaltrials.gov](https://clinicaltrials.gov) (Identifier: NCT04501874).

About EMB-001

EMB-001 is a patented combination product comprising two FDA-approved medications, the cortisol synthesis inhibitor metyrapone and the benzodiazepine oxazepam. The innovation is based on insights into the physiologic responses to stress in addiction. EMB-001 is thought to act by mechanisms distinct from those of existing addiction treatments and is hypothesized to reduce the increased activity in the stress response system induced by drugs, cues and stressors that contribute to relapse in addiction.

EMB-001 may potentially reduce the cravings and loss of control that drive relapse in addiction, by uniquely targeting multiple pathways, thereby possibly maximizing potential efficacy. Therapies that reduce cravings and relapse and thus result in long-term abstinence and recovery would be significant contributions to the treatment of a broad range of addictions.

About Embera NeuroTherapeutics

Embera NeuroTherapeutics, Inc. is a clinical-stage pharmaceutical company focused on treating a broad range of addictions where the major clinical challenge is a limited range of effective therapies. Embera is developing a novel drug combination (EMB-001) targeting specific brain functions related to stress responses that drive craving and relapse associated with these disorders. Embera is advancing EMB-001 development programs in cocaine use disorder and smoking cessation. www.emberaneuro.com

Note: The clinical research discussed in this press release was supported by the National Institute on Drug Abuse of the National Institutes of Health under grant number U01DA038879-01A1. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.

Company Contact

Gary Connor
Chief Operating Officer
gconnor@emberaneuro.com
207-281-2652

Media Contact

Kari Watson
MacDougall
kwatson@macbiocom.com
781-235-3060