



Embera NeuroTherapeutics Initiates Phase 1 Clinical Trial to Test EMB-001 as a Novel Treatment for Addictions

-- Dose administration to first subject represents a milestone in pharmaceutical industry pipeline for substance use disorders --

BOSTON and SHREVEPORT, La.—May 28, 2015—[Embera NeuroTherapeutics, Inc.](#), a specialty pharmaceutical company developing novel treatments for smoking cessation, cocaine use disorder and other addictions, today announced the first subject received the initial dose in a Phase 1 clinical trial evaluating EMB-001. A novel combination of the FDA-approved drugs metyrapone and oxazepam, EMB-001 is being investigated for the potential treatment of cocaine use disorder and other addictions such as tobacco and methamphetamine use disorders. The Phase 1 trial is being conducted at the Pennington Biomedical Research Center in Baton Rouge, Louisiana, with the support of TAB Clinical Trials, a contract research organization based in Cary, North Carolina.

The randomized, double-blind, combined single and multiple rising dose clinical trial will evaluate the safety and pharmacokinetics of EMB-001 in healthy adult volunteers who smoke. The estimated 24 patients to be enrolled in the study will be placed into three cohorts. In each cohort, six patients will be randomized to receive EMB-001 and two will receive placebo. Patients will receive a single dose of EMB-001 or placebo on the first day, followed two days later by twice daily doses for seven days. The low dose will be administered to the first cohort, and increasing doses are planned to be administered to the second and third cohorts, depending on results from prior cohorts. All planned doses are low relative to the maximum FDA-approved doses for the components, which is consistent with Embera's hypothesis, supported by published data that they may combine to have greater efficacy in reducing the stress response associated with quitting an addictive drug.

The primary endpoints are safety and tolerability. Pharmacokinetics of metyrapone, oxazepam and metyrapol, the primary metabolite of metyrapone, will be measured in plasma. In addition, tobacco use and craving measures will be evaluated as exploratory efficacy endpoints. Top-line data are anticipated by the end of 2015.

“Substance use disorders bring the highest medical costs to society among central nervous system disorders, yet there are very few treatments either approved or in clinical development,” said Michael Detke, M.D., Ph.D., Chief Medical Officer of Embera. “EMB-001 is unique as the drug components, metyrapone and oxazepam, have been used for decades and have the potential to synergistically reduce the stress response associated with quitting addictive drugs. This small, Phase 1 trial may yield important safety and pharmacokinetic data, along with potential preliminary signs of efficacy, to inform our plans for advancing EMB-001 through later stage clinical development.”

EMB-001 has been tested with promising results in a published pilot study in cocaine-dependent human subjects, as well as in published preclinical models of nicotine, cocaine and methamphetamine dependence. Nearly one million U.S. citizens suffering from cocaine use disorder have no approved treatment option, and current treatment options for tobacco use disorder have limited efficacy and/or pose safety concerns.

“This Phase 1 clinical trial is an enormous milestone for Embera NeuroTherapeutics. We are pleased to be administering drug/placebo to subjects in EMB-001’s first clinical trial on the path to regulatory approval for a disease, cocaine use disorder, where today there are no approved treatments,” said Bob Linke, Chief Executive Officer of Embera. “We are proud to be progressing in our mission to address serious needs in addiction disorders.”

More information about Embera’s Phase 1 clinical trial is available at [Clinicaltrials.gov](https://clinicaltrials.gov/ct2/show/study/NCT02406066) (Identifier: NCT02406066).

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 chronic 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 cues that contribute to the acquisition and maintenance of addiction.

EMB-001 may potentially reduce the cravings and loss of control that drive addiction by uniquely targeting multiple pathways, to maximize potential efficacy as well as minimize safety and tolerability concerns. Therapies that break these barriers and 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 response that drive craving and relapse associated with these disorders.

Embera is advancing EMB-001 development programs in smoking cessation and cocaine use disorder. www.emberaneuro.com

Contacts

Bob Linke
President and CEO
Embera NeuroTherapeutics, Inc.
617-719-9406
rlinke@emberaneuro.com

For Media:

Kari Watson or Courtney Colgan
MacDougall Biomedical Communications
781-235-3060
kwatson@macbiocom.com or ccolgan@macbiocom.com

###