Embera NeuroTherapeutics Announces Positive Topline Data from Phase 1b Cocaine Interaction Study of EMB-001

-- EMB-001 was well-tolerated and no new safety signals were observed when co-administered with cocaine --

-- Preparations are underway for advancement into Phase 2 studies for cocaine use disorder and tobacco use disorder --

BOSTON, Mass. and SHREVEPORT, La. – May 8, 2016 – Embera NeuroTherapeutics, Inc., a specialty pharmaceutical company developing novel treatments for cocaine, nicotine, and other addictions, today announced that EMB-001 was found to be well-tolerated in a Phase 1b cocaine interaction study, and no new safety signals were observed. Designed to evaluate the safety, tolerability, and pharmacokinetic effects of EMB-001 co-administered with cocaine, the study was supported by an $11.1 million grant awarded to Embera in July 2016 by the National Institute on Drug Abuse (NIDA), part of the National Institutes of Health (NIH).

"No serious adverse events occurred when combining EMB-001 and cocaine, indicating that EMB-001 can be used safely in active cocaine users," said Michael Detke, M.D., Ph.D., Chief Medical Officer of Embera. "We have previously shown promising preliminary efficacy of EMB-001 in a published pilot study in cocaine dependent human subjects. With the successful completion of this cocaine interaction trial, these studies pave the way for our planned Phase 2 clinical trial to evaluate the efficacy of EMB-001 in patients with cocaine use disorder."

The Phase 1b trial was a randomized, double-blind, placebo-controlled, 2-period crossover study to assess the safety and pharmacokinetics of EMB-001 and cocaine when administered in combination. The study enrolled 18 non-treatment seeking adults, ages 21 to 55, with cocaine use disorder. Subjects were randomized to receive EMB-001 or placebo twice daily for six days. On the seventh day of the study, patients received a final morning dose of EMB-001 or placebo, followed by an IV infusion of cocaine. Following a 7-day washout period, subjects then underwent a second 7-day dosing period with EMB-001 or placebo, whichever was not administered during the first dosing period, and again a cocaine infusion on the seventh day. Primary outcome measures were the incidence of treatment-emergent adverse events (TEAEs) and changes in vital signs and electrocardiogram readings. Secondary outcome measures were the pharmacokinetics of EMB-001 and cocaine. Additional information on the trial can be found at clinicaltrials.gov, identifier number NCT02856854.

No clinically significant changes in blood pressure or heart rate were observed when cocaine was co-administered with EMB-001 versus placebo and no serious adverse events were recorded. The most common TEAEs reported were euphoric mood, somnolence, headache, and ACTH increases and/or cortisol decreases; the finding of euphoric mood is consistent with the known

effects of cocaine and the others are known to be associated with metyrapone and oxazepam, the active ingredients in EMB-001. 93% of all TEAEs were categorized as mild on the standard mild-moderate-severe clinical trial rating scale. Pharmacokinetic evaluation demonstrated that there were no significant increases in the maximum concentration of cocaine or its major metabolites in the bloodstream when co-administered with EMB-001 compared to placebo.

It is estimated that 18.2 million people worldwide, about 0.4 percent of the global population age 15 to 64 years, use cocaine. In the U.S. alone, nearly 1.9 million cocaine users, aged 12 or older, were reported in 2015. Despite this, there are currently no approved medications for the treatment of cocaine use disorder.

"The completion of this drug-drug interaction study is an important milestone for EMB-001, which is one of the leading drugs in development for cocaine use disorder," said Bob Linke, Chief Executive Officer of Embera. "Since the mechanism of EMB-001 is hypothesized to target the stress response that contributes to relapse in addiction, we believe that EMB-001 can be applicable in other addictions including nicotine, and we are excited to begin a tobacco use disorder efficacy trial in the second half of 2017."

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 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, thereby possibly maximizing potential efficacy as well as minimizing safety and tolerability concerns. 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.

Contacts

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

For Media:
Kari Watson
MacDougall Biomedical Communications
781-235-3060
kwatson@macbiocom.com