



Embera NeuroTherapeutics Receives \$11M Grant from National Institute on Drug Abuse for the Clinical Development of EMB-001 for the treatment of Cocaine Addiction

BOSTON, Mass. and SHREVEPORT, La. – July, 26, 2016 – [Embera NeuroTherapeutics, Inc.](#), a specialty pharmaceutical company developing novel treatments for cocaine, nicotine, and other addictions, today announced that it has received an \$11.1 million, three-year grant from the National Institute on Drug Abuse (NIDA), part of the National Institutes of Health (NIH). The grant will support continued clinical development of EMB-001 for the treatment of cocaine addiction, which is clinically termed “cocaine use disorder.”

In 2014, the US had 1.5 million current cocaine users aged 12 or older. Despite this, no approved medications exist for the treatment of cocaine use disorder. EMB-001 is a novel candidate for the treatment of addiction based on the discoveries of Dr. Nicholas Goeders, Professor and Head of the Department of Pharmacology, Toxicology & Neuroscience at the Louisiana State University (LSU) Health Sciences Center, and licensed exclusively to Embera by LSU. A patented combination of the FDA-approved drugs metyrapone and oxazepam, EMB-001 targets the stress response system as a novel approach to addressing addiction and relapse. The potential utility of EMB-001 in cocaine, nicotine and methamphetamine addiction has been demonstrated in preclinical studies, and clinical activity has been demonstrated in a pilot study in cocaine-dependent human subjects. Embera also recently announced the successful completion of a Phase 1 study of the safety and tolerability of EMB-001.

“We are delighted to receive this positive validation and support from NIDA for EMB-001, the leading product in clinical development for cocaine use disorder, for which there are currently no FDA-approved medications,” said Robert Linke, Chief Executive Officer of Embera.

“We have seen encouraging results in a pilot study of EMB-001 in cocaine-dependent patients and, with this support, we are excited to continue the advancement of our lead candidate through a Phase 2 proof-of-concept efficacy study,” said Michael Detke, M.D., Ph.D., Chief Medical Officer of Embera.

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 will be supported by the National Institute On Drug Abuse of the National Institutes of Health under Award Number U01DA038879. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.

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