



Embera NeuroTherapeutics Completes Series B Financing and Receives Grants to Advance EMB-001 into Phase 2 Clinical Studies in Cocaine Use Disorder and Smoking Cessation

-- Embera appoints Bruce McCarthy, M.D. as Chief Medical Officer --

-- Gary Connor, RN promoted to Chief Operating Officer --

BOSTON and SHREVEPORT, La. - December 19, 2019 - [Embera NeuroTherapeutics, Inc.](#), a specialty pharmaceutical company developing novel treatments for cocaine, nicotine, and other addictions, today announced completion of its Series B financing and the receipt of two grant awards which will fund Phase 2 clinical studies for EMB-001 in cocaine use disorder and smoking cessation. EMB-001 is designed 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.

The Series B financing included participation from Embera's existing investors. The funding will support Embera's operations as the company focuses on advancing EMB-001 through Phase 2 studies.

The first grant comes from the National Institute on Drug Abuse of the National Institutes of Health (NIDA) and is the final portion of the three-year grant award which totaled \$11.1 million. This award will fund a Phase 2 efficacy study of EMB-001 in cocaine use disorder.

The second grant award is from the Rose Research Center (RRC) in North Carolina, which will evaluate EMB-001 as a potential smoking cessation product in a Phase 2a efficacy clinical study. The study will be part of RRC's five-year grant from the Foundation for a Smoke-Free World to evaluate effective smoking cessation treatments. As part of the Rose Research Center award, Embera received a grant from the Foundation for a Smoke-Free World to support the manufacturing of EMB-001 clinical trial material for the study.

Both Phase 2 studies are expected to begin dosing subjects in the first quarter of 2020.

"We are excited to fund and investigate EMB-001 in Phase 2a clinical study in smoking cessation," said Dr. Jed Rose, President and CEO of Rose Research Center. "EMB-001 simultaneously modulates multiple pathways in the human stress response and is a promising candidate as we elucidate the biological mechanisms underlying tobacco addiction on our mission to promote the development of more safe and effective treatments to address what remains a major unmet need."

“The grant awards from NIDA and RRC as well as the continued support from our investors put our drug on the path to potentially change addiction treatment,” said Bob Linke, President and CEO of Embera. “Cocaine overdose remains a serious issue in the United States where there are currently no approved treatments. Smoking continues to be the leading preventable cause of death. There is a real need for an effective treatment option to address these addiction disorders.”

Embera today also announced the addition of Bruce McCarthy, M.D. to the leadership team as Chief Medical Officer. Dr. McCarthy previously led neuroscience development programs at Abbott and Pfizer as well as a development stage neuroscience company, Afferent. In addition, Gary Connor, RN, has been named Chief Operating Officer and will continue his responsibilities as Vice President of Clinical Operations overseeing all operating functions of the company.

“We are pleased to welcome Dr. McCarthy to our executive team,” said Bob Linke. “Dr. McCarthy’s expertise and experience will add unparalleled breadth and depth to our clinical development as we advance EMB-001 into two important Phase 2 clinical studies. We also look forward to Gary’s expanded leadership role as COO. He joined Embera as EMB-001 entered clinical development and has played a pivotal role overseeing EMB-001 clinical operations from IND filing through initiation of Phase 2 development.”

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 cocaine use disorder 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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