



Embera NeuroTherapeutics Announces First Subject Dosed in Phase 2a Study of EMB-001 in Smoking Cessation

Dennis Purcell, Founder of Aisling Capital, joins Board of Directors

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BOSTON & SHREVEPORT, La.--(BUSINESS WIRE)--Embera NeuroTherapeutics, Inc., a specialty pharmaceutical company developing novel treatments for cocaine, nicotine, and potentially other addictions, today announced that the first subject has been dosed in a Phase 2a smoking cessation study for the treatment of tobacco use disorder. EMB-001 is designed to help patients struggling with addiction 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 also announced that Dennis Purcell, the Founder of Aisling Capital, has joined the Board of Directors.

“Smoking cessation therapies have undoubtedly improved outcomes, however even when treated with the most successful approved interventions, over 75% of patients resume smoking within a year,” said Bruce McCarthy, M.D., Chief Medical Officer, Embera NeuroTherapeutics. “EMB-001 may reduce the neurophysiological activation of cues, stress and other triggers that lead to cigarette use in patients who are quitting smoking. This is an entirely new approach from marketed therapies, that could potentially be used in conjunction with approved therapies which work by blocking the ‘high’ of an addictive substance or by providing a substitute for the addictive substance. In a Phase 1 Safety study, EMB-001 was well-tolerated and signals of efficacy were observed. This Phase 2a study will help us better understand the efficacy of EMB-001 in helping subjects stop smoking.”

The Phase 2a open label clinical trial will enroll between 25 and 50 subjects for a 12-week treatment period and Embera expects to report topline results in Q1 2022. Current investors in Embera participated in a \$1.3 million financing to support the EMB-001 Phase 2a tobacco use disorder clinical study.

Embera previously announced the initiation of a Phase 2 trial of EMB-001 in cocaine use disorder which is also expected to produce topline results in Q1 2022. Over 70% of subjects have been enrolled in the 80 subject cocaine use disorder trial.

Embera also announced that Dennis Purcell, Founder of Aisling Capital LLC, has joined the Board of Directors.

“Dennis Purcell brings an unparalleled record of accomplishment in biotech to the Board of Embera NeuroTherapeutics as the Company completes two important Phase 2 proof-of-concept clinical studies,” said Bob Linke, Executive Chairman of Embera. “Dennis’s role in the growth of the biotech industry has been widely recognized. He was inducted into the Biotech Hall of Fame by Genetic Engineering News, named to the Biotechnology All-Stars list by Forbes ASAP, honored as one of

the top 50 Irish-American businessmen and cited as one of the top 100 contributors to the biotechnology industry. We look forward to benefiting from Dennis's expertise and experience as Embera advances EMB-001 through clinical development with the goal of providing a new treatment option for people fighting addictions."

Prior to founding Aisling Capital, a fund with over \$1.8B in committed capital advancing healthcare technologies, Mr. Purcell served as Managing Director of the Life Sciences Investment Banking Group at Chase H&Q for over 5 years. While at H&Q, he was directly involved with over two hundred completed transactions and supervised over \$10 billion of financing and advisory assignments in the pharmaceutical, biotechnology and medical products industries. During his tenure, BioWorld and other industry publications cited H&Q as the leading underwriter of life sciences securities. Prior to joining H&Q, Mr. Purcell was a Managing Director in the Healthcare Group at PaineWebber, Inc.

"Addiction remains a devastating disease in the United States and globally," said Dennis Purcell. "EMB-001 has the potential to offer a new approach to treating addiction by reducing the cravings and loss of control that drive relapse. I look forward to working with the team at Embera as we advance EMB-001 in the clinic for the treatment of smoking cessation and cocaine addiction."

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 EMB-001 cocaine use disorder 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.

In addition, manufacturing of EMB-001 drug product for use in the Phase 2a tobacco use disorder clinical trial was supported by a grant from the Foundation for a Smoke Free World.

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