

Media Release

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Synosia Therapeutics Initiates Study of Potential First Drug Therapy for Cocaine Dependence

Phase IIa trial of nepicastat (SYN 117) starts enrolment

Basel, Switzerland, July 30, 2008 – Synosia Therapeutics today announced the start of a clinical trial to evaluate what could become the first drug therapy to treat cocaine dependence.

The double-blind, placebo-controlled, Phase IIa trial enrolling non-treatment-seeking cocaine-dependent volunteers at the University of Texas Medical Branch at Galveston is investigating the safety and efficacy of nepicastat (SYN-117), a selective dopamine β -hydroxylase (DBH) inhibitor when administered with cocaine.

One of the key objectives of the study is to evaluate the effect of nepicastat on the subjective response to cocaine and includes a number of measures of the rewarding effects of cocaine. Modulation of the subjective experience of cocaine is believed to be predictive of clinical efficacy in the treatment of cocaine dependence.

“One of the advantages of investigating nepicastat is the existence of clinical data to indicate its safety in congestive heart failure patients,” said Professor Kathryn Cunningham, principal trial investigator and Professor of Pharmacology and Director of Center for Addiction Research at the University of Texas Medical Branch. “The cardiovascular safety data gives us a big head start in assessing the potential of nepicastat to reduce craving and to modulate the body’s response to cocaine.”

“Cocaine dependence is an important public health problem in the United States and Europe, but it’s been somewhat of a neglected area in terms of medical research” said Synosia’s chief executive officer and president Ian Massey. “There are no medications currently available to treat cocaine dependence specifically. Current treatment focuses on cognitive behavioral therapy but we believe there is a real opportunity to develop a drug therapy that would change the way the body responds to cocaine.”

The National Institute on Drug Abuse estimates that 1.5 million Americans could be classified as dependent on or abusing cocaine and that over 900,000 of these are seeking treatment.¹ In Europe, after opioids and cannabis, cocaine is the drug most commonly reported as the reason for entering treatment.²

Cocaine is a potent central nervous system stimulant which can powerfully stimulate the dopaminergic reward system by releasing unnaturally high amounts of dopamine, leading to a euphoric experience and consequent potential for abuse and dependence.

About Nepicastat (SYN-117)

Nepicastat was discovered and developed by Roche, which initially investigated it as a potential treatment for congestive heart failure. Phase II clinical development demonstrated that the compound had a good safety profile and was well tolerated.

In 2007, Roche granted licensing rights to Synosia Therapeutics to develop nepicastat for all neurological and psychiatric indications.

The central role of DBH in cocaine addiction is supported by both clinical and preclinical studies. Nepicastat has the potential to help patients withdraw from cocaine and to prevent relapse. Synosia is also investigating nepicastat for the treatment of post-traumatic stress disorder.

About Synosia Therapeutics

Synosia Therapeutics develops and intends to commercialise innovative and clinically differentiated products for unmet medical needs in psychiatry and neurology. The privately-owned company has in its pipeline six clinical-stage compounds acquired through key partnerships with Novartis, Roche and Syngenta. Two of the compounds are marketed drugs being tested in new indications to extend their reach into neurological and psychiatric diseases with high unmet medical need, including anxiety and Parkinson’s disease. Synosia’s headquarters is in Basel, Switzerland. For more information visit www.synosia.com

References

1. National Institute on Drug Abuse, Research Report Series – Cocaine Abuse and Addiction
<http://www.drugabuse.gov/ResearchReports/Cocaine/Cocaine.html>
2. European Monitoring Centre for Drugs & Drug Addiction – Cocaine and crack cocaine
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