

## Media Release

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### **US Department of Defense to Fund Trial Using Novel Compound from Synosia Therapeutics**

#### ***Nepicastat (SYN-117) To Be Tested for the Treatment of Post-Traumatic Stress Disorder***

**South San Francisco, CA, July 24, 2008** – The United States Department of Defense (DoD) will fund a Phase II, multi-site clinical trial of nepicastat (SYN-117) for the treatment of post-traumatic stress disorder (PTSD), Synosia Therapeutics announced today.

The trial, conducted by three leading researchers in the field of PTSD, will be a six-week, prospective, randomized, double-blind, placebo-controlled study of nepicastat, a dopamine  $\beta$  hydroxylase (DBH) inhibitor, in 90 veterans of Operation Iraqi Freedom and Operation Enduring Freedom. It will be followed by an eight-week extension phase.

The primary aim of the study is to assess the efficacy and tolerability of nepicastat in the treatment of PTSD-induced hyperarousal, with the secondary aims of assessing its ability to improve other symptoms of PTSD, induce remission and improve quality of life.

Funding of \$1.4 million from the DoD Post Traumatic Stress Disorders Research Program will be provided to support the study, being conducted by investigators at three medical centers:

- Lori L. Davis, M.D., initiating principal investigator (PI) for the study and professor of psychiatry, School of Medicine, University of Alabama at Birmingham, and chief of research service at the Tuscaloosa Veterans Affairs (VA) Medical Center
- Tom Kosten, M.D., Jay H Waggoner chair and professor of psychiatry and neuroscience at Baylor College of Medicine and research director of the (VA) National Substance Use Disorders Quality Enhancement Research Initiative (QUERI), based at the Michael E. DeBakey VA Medical Center in Houston

- Mark Hamner, M.D., professor of psychiatry and director of PTSD clinical and clinical research section, Ralph H. Johnson VA Medical Center in Charleston, South Carolina.

“The mechanism of action of this new compound directly inhibits the conversion of dopamine to norepinephrine, a key neurotransmitter reported in previous studies by Dr. Kosten to be associated with hyperarousal and hypervigilance, common and distressing symptoms of PTSD,” Dr. Davis explained. “PTSD is a major public health problem for active duty personnel, veterans and civilians. This novel treatment offers hope for improving health outcomes for all trauma survivors.”

“We are very pleased to have three leading researchers express interest in the potential of one of our compounds to treat post-traumatic stress disorder,” said Ian Massey, Synosia chief executive officer and president. “It’s an additional milestone for the company to have the investigators’ grant proposal selected for funding by the U.S. government in a competitive review process.”

The first patients are expected to be enrolled in the trial in September 2008.

#### **About Post-Traumatic Stress Disorder**

Post-Traumatic Stress Disorder (PTSD) is an anxiety disorder that can develop after exposure to a major traumatic event or ordeal in which grave physical harm occurred or was threatened.

Once associated mainly with veterans of the Vietnam War and subsequent conflicts, PTSD is now recognized in even greater numbers among civilians exposed to traumatic events. It may be accompanied by depression and substance abuse.

#### **About Nopicastat (SYN-117)**

Nopicastat inhibits dopamine  $\beta$ -hydroxylase (DBH), the enzyme responsible for the conversion of dopamine into norepinephrine. Nopicastat has been shown to increase brain and blood concentrations of dopamine and decrease those of norepinephrine in animals.

Nopicastat is administered orally and has been well tolerated in studies including over 250 people in other therapeutic indications, some receiving treatment for several months.

Rights to nopicastat were obtained from Roche in 2007. In addition to PTSD, Synosia is soon expected to initiate studies evaluating nopicastat in drug dependency.

#### **About Synosia Therapeutics**

Synosia Therapeutics develops and intends to commercialize innovative and clinically differentiated products for unmet medical needs in psychiatry and neurology. The privately-owned company has six clinical-stage compounds in its pipeline acquired through key partnerships with Novartis, Roche and Syngenta. Two of the compounds are marketed drugs being tested in new indications, extending 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 and has a subsidiary company in the United States. For more information visit [www.synosia.com](http://www.synosia.com)

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