



## *Media Release*

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## **Synosia Therapeutics' SYN-115 Improves Motor and Non-Motor Function in Patients with Mild- to-Moderate Parkinson's Disease**

### **Results from clinical study of potential first-in-class treatment presented at American Academy of Neurology meeting today**

**SAN FRANCISCO, USA, April 14, 2010** – Synosia Therapeutics today announced the presentation of data from a phase 2a clinical study of the company's adenosine 2a (A2a) receptor antagonist (SYN-115) in Parkinson's disease. The data demonstrate that SYN-115 significantly improves measures of motor and non-motor function in patients with Parkinson's disease (PD) either alone or in combination with levodopa. The results also clearly illustrate the value of perfusion magnetic resonance imaging (MRI) as a tool to rapidly evaluate the pharmacodynamic effects of new drugs in the brain. Findings will be presented today at the American Academy of Neurology 62<sup>nd</sup> Annual Meeting in Toronto, Ontario, Canada.

"These data provide clear evidence that SYN-115 penetrates the brain and produces changes in the activity of regions known to be sensitive to drugs used to treat Parkinson's. These changes accompany significant improvements in selected measures of motor and non-motor functions in these patients," said Dr Kevin J. Black, associate professor of psychiatry, neurology, radiology and neurobiology at the Washington University School of Medicine in St. Louis, Missouri, and principal investigator for the phase 2a study. "Additionally, through the successful utilization of perfusion MRI to assess the impact of SYN-115 in specific regions of the brain, this study clearly demonstrates the utility of this technique to provide rapid, useful and clinically relevant information for the evaluation of new drugs for the treatment of CNS disorders."

The phase 2a trial was a randomized, double-blind, placebo-controlled, cross-over study in patients with mild-to-moderate Parkinson's disease. Patients were randomized to one week each of SYN-115, washout, and then matching placebo, or the reverse. Effects of 60 mg BID (N= 14) and 20 mg BID

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(N=13) of SYN-115 in the absence of levodopa and in the presence of a low dose of levodopa were evaluated using a number of techniques, including functional magnetic resonance imaging (fMRI), clinical ratings such as the Unified Parkinson's Disease Rating Scale (UPDRS), tapping speed, and cognitive tests.

The data presented today demonstrate that, after correction for whole-brain CBF effects and for multiple comparisons, SYN-115 produced highly significant, dose-responsive decreases in cerebral blood flow in regions of the brain known to be relevant to Parkinson's. These decreases are entirely consistent with the expected mechanism of action of SYN-115.

In the 60 mg cohort, tapping speed was improved (faster) by SYN-115 as compared to placebo, both before (5 percent,  $p=0.03$ ) and during a sub-therapeutic IV infusion of levodopa (6 percent,  $p=0.02$ ).

Total UPDRS motor score was 20 percent lower (improved) with SYN-115 as compared to placebo when administered with levodopa ( $p=0.09$ ). Considering UPDRS items individually, 10 of 13 items were better on SYN-115 than on placebo; improvement in two UPDRS measures of bradykinesia (finger taps and rapidly alternating movements of the hands) achieved statistical significance. Performance on the go/no-go task, a cognitive test considered to depend on dopaminergic function, was also significantly improved by SYN-115 as compared to placebo. SYN-115 was well tolerated at both the 60 and 20 mg BID doses.

"The results for this study give us confidence that SYN-115 is having the anticipated and desired effects in the brain and has high potential to become an innovative medicine for the treatment of the motor and non-motor symptoms of Parkinson's disease," said Dr. Ian Massey, Synosia's chief executive officer and president. "Based on these important and exciting findings, we plan to initiate additional clinical studies to further evaluate the efficacy and safety of SYN-115."

### **About SYN-115**

SYN-115 is a potent and selective inhibitor of the A2a receptor. Synosia is developing the compound for the treatment of Parkinson's disease. Synosia obtained rights to SYN-115 from Roche (SIX: RO, ROG; OTCQX: RHHBY) in 2007 for development in selected indications of the central nervous system.

### **About Parkinson's Disease**

Parkinson's disease is the second most common neurodegenerative disorder, after Alzheimer's disease. It affects about one percent of people ages 65-69, rising to up to three percent of people who are 80 years and older.<sup>1</sup> Parkinson's disease manifestations result from decreased dopamine production in the brain. Dopamine is a neurotransmitter that plays an important role in muscle control.

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## About Synosia

Synosia Therapeutics is a privately owned company, which develops and intends to commercialise innovative, first or best-in-class products for unmet medical needs in neurology and psychiatry. Synosia utilises cutting-edge technologies and creative clinical study designs to de-risk its compounds before moving into larger, more extensive Phase II and Phase III programmes.

Synosia has five clinical-stage compounds in development for neurological and psychiatric diseases that have high unmet medical need, including Parkinson's and Alzheimer's disease. Synosia is headquartered in Basel, Switzerland. For more information visit [www.synosia.com](http://www.synosia.com)

## References

1. Gutmacher et al. Alzheimer's Disease and Parkinson's Disease. New England Journal of Medicine (2003); 348; 1356-64

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