

## Media Release

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#### Contact Synosia Therapeutics

Julie Walters at Tudor Reilly

Tel: +44 (0) 1494 753 990

Mobile +44 (0) 775 3626967

[julie.walters@tudor-reilly.com](mailto:julie.walters@tudor-reilly.com)

In the US

Michele Parisi at Tudor Reilly

Tel: +1 925 864 5028

[michele.parisi@tudor-reilly.com](mailto:michele.parisi@tudor-reilly.com)

In Switzerland:

Martin Meier-Pfister or Jan Gregor

at The IR Firm

Tel: +41 43 244 81 54

Mobile: +41 79 652 36 20

[synosia@ifirm.biz](mailto:synosia@ifirm.biz)

## Synosia Starts Phase II Efficacy Trial For Rufinamide

### - Epilepsy Drug to be Tested as Treatment for Anxiety -

**Basel, Switzerland, March 31, 2008** – Synosia Therapeutics today announced the start of a multi-site, Phase II clinical trial to evaluate the efficacy of rufinamide (SYN-111), a sodium channel blocker, as a potential treatment for general anxiety disorder.

The trial is an eight-week, double-blind, placebo-controlled, exploratory study being conducted in 20 sites in the United States. It will assess the efficacy and tolerability of rufinamide in up to 230 patients with general anxiety disorder, as measured by multiple psychometric assessment tools. Patients randomized to rufinamide will receive 250mg twice a day for one week followed by 500mg twice a day for seven weeks. The trial design was guided by the encouraging results of a proof-of-concept study announced in January 2008.

Rufinamide was discovered and developed by Novartis. Rights to SYN-111 were obtained by Synosia from Novartis in 2007 in an exclusive worldwide licensing agreement, outside of Japan, to develop and commercialize rufinamide for the treatment of anxiety and other mood disorders. Rufinamide is also marketed by Eisai in Europe as a drug to treat a form of epilepsy under the tradename Inovelon®.

“Given the extensive safety experience available from previous studies, we believe this structurally novel compound has the potential to relieve anxiety without the adverse side effects of current treatments,” said Stephen Bandak, Synosia’s chief medical officer. “There is a real need for new treatment options without the limited compliance associated with selective serotonin reuptake inhibitors (SSRIs) or the risk of dependence of benzodiazepine-based treatments.”

It is estimated that over 62 million people in the United States and the five major European pharmaceutical markets suffer from a form of anxiety. Of those, over nine million suffer from general anxiety disorder.<sup>1, 2</sup>

### **About Rufinamide**

The drug was originally discovered and developed by Novartis, which in 2004 granted certain licensing rights to Eisai, excluding anxiety and mood disorders. In January 2007, Eisai received marketing authorisation in the European Union for Inovelon® (rufinamide) as adjunctive anti-epileptic therapy in Lennox-Gastaut Syndrome (LGS), a severe form of epilepsy that develops in early childhood. The extensive clinical development program for rufinamide in epilepsy has generated over 2500 patient years of exposure to the drug.

### **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. Synosia's pipeline includes two marketed drugs that will be 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. For more information visit [www.synosia.com](http://www.synosia.com)

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Synosia Therapeutics is providing this communication as of this date and does not undertake to update any forward-looking statements contained herein as a result of new information, future events or otherwise.

### **References**

1. Demyttenaere et al. Prevalence, Severity, and unmet needs for treatment of mental disorders in the WHO World Mental Surveys. JAMA (2004) vol. 291 (21) pp. 2581-90.
2. Kessler et al. Lifetime prevalence and age-of-onset distributions of DSM-IV disorders in the National Comorbidity Survey Replication. Arch Gen Psychiatry (2005) vol. 62 (6) pp. 593-602.

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