



## **PRESS RELEASE**

# **Psyadon Pharmaceuticals, Inc. Announces Regulatory Milestones and the Initiation of a Clinical Trial of Ecopipam in Lesch-Nyhan Disease**

GERMANTOWN, MD, February 9, 2010

Psyadon Pharmaceuticals, Inc. today announced that the United States Food and Drug Administration (FDA) has accepted its Investigational New Drug Application (IND) to study ecopipam in patients with Lesch-Nyhan Disease (LND). The first center at which the drug will be evaluated is Emory University under the direction of Dr. Hyder A. Jinnah, MD, PhD. The study is designed to evaluate the safety and tolerability of different doses of ecopipam in adults (group 1), adolescents (group 2) and children (group 3) with LND.

Dr. Jinnah is a world-renowned expert in the molecular biology and clinical pathology of LND having published numerous peer-reviewed articles. He believes that dopamine D1-receptor antagonists like ecopipam have “the potential to significantly ameliorate the behavioral symptoms seen in these patients.”

“We are very excited to be starting our clinical trial with ecopipam in patients with Lesch-Nyhan Disease. There are currently no treatments available for these patients, and we are hopeful that this drug will provide some benefit,” said Richard E. Chipkin, PhD, President and CEO of Psyadon Pharmaceuticals.

Ecopipam is a selective antagonist of the D1-family of dopamine receptors. Psyadon Pharmaceuticals licensed worldwide rights to ecopipam from Schering-Plough Corporation, an affiliate of Merck & Co., Inc. in 2008. Although an optimal clinical indication has not yet been identified, ecopipam has already been studied in over 2,000 patients.

LND is a rare genetic disorder that is predominantly seen in males. The patients have a well-studied mutation of a specific enzyme which causes a characteristic metabolic, motor, and behavioral syndrome. The onset of disease is usually between ages 1-3 years, and patients suffer life-long debilitation. It has been estimated that in the United States there are between 500 and 1000 patients.

## **ORPHAN DRUG DESIGNATION**

Psyadon Pharmaceuticals has received orphan drug designation for the use of ecopipam in LND in both the United States and the European Union. This provides market exclusivity and other benefits in these territories.

## **PSYADON PHARMACEUTICALS**

Psyadon Pharmaceuticals is a pharmaceutical company dedicated to the discovery and development of drugs for serious neurological and psychiatric disorders. The company was founded in 2004 under the name Ruxton Pharmaceuticals.

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