FDA Grants Orphan Drug Designation for Mithridion's MCD-386CR to Treat Progressive Supranuclear Palsy

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MADISON, Wis., May 9, 2011 /PRNewswire/ -- Mithridion, Inc., a privately-owned clinical stage drug development company focusing on serious Central Nervous System (CNS) disorders, announces that the U.S. Food and Drug Administration (FDA) has awarded Orphan Drug designation for MCD-386CR, its lead drug candidate, for the treatment of Progressive Supranuclear Palsy (PSP).

Orphan status entitles Mithridion to seven years of market exclusivity upon approval of MCD-386 for treating PSP, and to apply for grant funding to contribute to clinical trial costs, tax credits, and a waiver of certain FDA fees. Orphan status is intended to encourage the development of drugs for diseases affecting fewer than 200,000 persons in the USA.

PSP is a progressive brain disease in which neurons degenerate in regions of the brain vital for eye movements, balance, walking, speech, and cognition. Cognitive impairment typically involves slowed thinking, and difficulties with reasoning, planning, and shifting between tasks, caused by dysfunction of the brain's executive functions. This has been called "dysexecutive syndrome."

"Orphan status will help us immeasurably to bring together the resources and support needed to evaluate MCD-386CR in this rare but important disease, and indeed in other devastating brain diseases for which there are no current therapies," said Trevor M. Twose, Ph.D., the company's Chief Executive. "Based on results in preclinical studies, we believe MCD-386CR potentially will help restore cognition, so vital to human functioning, and potentially could treat the underlying processes causing the degeneration of neurons in PSP."

As a part of its recently-articulated strategy, Mithridion is actively exploring opportunities to develop its drug candidates in niche market opportunities in serious CNS or brain disorders, in addition to more common diseases, such as Alzheimer's disease and schizophrenia. Several promisi
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