Marinus Pharmaceuticals Announces Commencement of Phase 2 Trial of Ganaxolone for the Treatment of Posttraumatic Stress Disorder

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BRANFORD, Conn., April 21, 2011 /PRNewswire/ -- Marinus Pharmaceuticals, Inc., the leader in the development of neurosteroids for central nervous system disorders, today announced commencement of a proof-of-concept clinical trial of its lead candidate ganaxolone for the treatment of posttraumatic stress disorder (PTSD). Ganaxolone modulates inhibitory GABA-A receptors, possibly at a specific neurosteroid recognition site. Neurosteroid levels have been implicated in both the severity and treatment outcome in PTSD patients.

"This trial will test the hypothesis that a neurosteroid analog of allopregnanolone will be beneficial in the treatment of PTSD and augment our existing safety database for ganaxolone in humans," stated Gail Farfel, Ph.D., Chief Development and Regulatory Officer of Marinus. "Achieving full remission of PTSD symptoms is difficult with current treatments for PTSD. New options that can increase efficacy are needed for the growing population of PTSD patients worldwide."

This randomized, double-blind, placebo-controlled clinical trial is being conducted by the INTRuST Consortium to evaluate the safety, tolerability and efficacy of oral ganaxolone after six weeks of dosing in patients with PTSD. The INTRuST Consortium is a group of clinical study centers in the United States funded by a Department of Defense award to advance treatments and medical research in PTSD and traumatic brain injury. This public-private collaboration will study ganaxolone under Marinus' Investigational New Drug Application (IND) filed with the Food and Drug Administration (FDA). The trial will take place in the United States and is designed to enroll approximately 120 PTSD patients.

"Ganaxolone has been shown in clinical studies to be efficacious and well tolerated in refractory epilepsy patients, and we expect the INTRuST PTSD trial to expand ganaxolone's profile into neurosteroid-mediated psychiatric disorders," said Kenneth Shaw Ph.D., Senior Vi
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