

Marinus Pharmaceuticals, Inc. Announces Positive Results of its Phase 2 Clinical Trial of Ganaxolone as Adjunctive Therapy in Adults with Partial Onset Seizures

BRANFORD, Conn., March 3, 2009 -- Marinus Pharmaceuticals, Inc. today announced that it met its primary endpoint for its Phase 2 clinical trial investigating the safety and efficacy of ganaxolone as adjunctive therapy in adults with partial onset seizures, a type of epilepsy. In this trial, ganaxolone demonstrated a statistically significant reduction in seizures versus placebo. Efficacy was seen in the first week of dosing. Ganaxolone was also found to be safe and well-tolerated in this population adding to the safety database of more than 950 subjects.

Partial seizures are episodes of abnormal electrical activity in the temporal lobe of the brain, an area near the side of the head, resulting in unconsciousness with symptoms of decreased responsiveness and decreased awareness of self and surroundings. Partial seizures occur in about 35 percent of people with epilepsy.

"This is a major milestone validating the effectiveness of ganaxolone, as a novel first in class anticonvulsant drug. Ganaxolone is the only neurosteroid in clinical development and is a unique GABA modulator that will expand the armamentarium of drugs available to treat epilepsy. The novel mechanism of action and excellent safety profile of this compound also has the potential to specifically address the unique needs of women with epilepsy," commented John Krayacich, president and CEO of Marinus Pharmaceuticals, Inc. "We look forward to continuing the development of ganaxolone for epilepsy as well as exploring its unique mechanism of action in other central nervous system (CNS) indications such as post traumatic stress disorder and postpartum depression. We believe patients with these and other CNS disorders may benefit from this unique compound."

The Phase 2 trial was a randomized, double-blind, placebo-controlled trial evaluating ganaxolone as add-on therapy for adults with partial onset seizures, who continued to have seizures even while taking up to three antiepileptic drugs (AED). The trial enrolled 147 patients at 24 sites in the U.S. Patients were observed for baseline seizure activity for 8 weeks and were then randomized to receive either ganaxolone or placebo in addition to their existing stable AED regimen. Patients entering the trial were experiencing, on average, 8 to 11 seizures per month. The most common background AEDs in the trial were lamotrigine, levetiracetam, carbamazepine, and topiramate.

Patients randomized to the ganaxolone treatment arm were titrated over one to two weeks to a maintenance dose of 1,500 mg/day where they were maintained for an additional 8 weeks. Patients in the ganaxolone arm met the primary endpoint showing a statistically significant reduction of mean weekly seizure frequency vs. the placebo arm during the titration and maintenance period ($P < 0.0251$). In addition, the patients in the ganaxolone arm also showed an improvement on percent reduction in seizure frequency vs. placebo ($P < 0.0144$). Responder rates (patients with greater than 50 percent reduction in seizures) were numerically larger in the ganaxolone arm vs. placebo but did not reach statistical significance in this study ($P < 0.1926$).

"It is encouraging to see these positive results for a novel compound such as ganaxolone," states Joyce Cramer, president of the Epilepsy Therapy Project. "Thirty percent of epilepsy patients still do not have their epilepsy controlled with current antiepileptic drugs. There is a clear need for new treatment options, especially drugs with new mechanisms of action to complement the currently available therapies."

Ganaxolone was generally well tolerated with the majority of patients able to escalate and maintain the 1500 mg/day dose. The discontinuation rates due to adverse events between placebo and ganaxolone arms were 6 percent and 7 percent, respectively. The most commonly reported adverse events were CNS-related and were mild to moderate in severity. Common adverse events experienced by more than 5 percent of subjects included dizziness, fatigue, somnolence, headache, abnormal coordination, falls, nasopharyngitis (an inflammation of the nasal passages) and convulsion. No deaths were reported in this study.

All patients completing the double blind portion were eligible to enter an open label extension trial, with 95 percent of patients electing to continue therapy. Based on these results, Marinus is planning a dose-ranging Phase 2b program with ganaxolone.

About Ganaxolone

Ganaxolone is a synthetic neurosteroid and a derivative of the naturally occurring neuromodulator, allopregnanolone. It is being investigated as a first in class treatment for epilepsy. Ganaxolone has been administered to more than 950 healthy adult volunteers and patients in more than 35 Phase 1 and Phase 2 studies. Early epilepsy studies involved more than 100 patients and generated data supportive of the efficacy and safety of ganaxolone in the treatment of both children and adults suffering from refractory epilepsy (patients who continue to have seizures despite taking multiple anticonvulsant drugs).

Marinus has successfully developed several proprietary and novel patented formulations of ganaxolone.

About Marinus Pharmaceuticals

Marinus is a specialty pharmaceutical company dedicated to the reformulation, development, and commercialization of novel drugs to treat serious neurological, psychiatric, and pain disorders. Marinus is located in Branford, Connecticut. Its investors include Domain Associates, Canaan Partners, Sofinnova Ventures and Foundation Medical Partners. For additional information, please visit the company's Web site at www.marinuspharma.com.

About Epilepsy

Epilepsy is a chronic neurologic condition that affects more than fifty million people worldwide and nearly three million people in the United States. Epilepsy is characterized by recurrent unprovoked seizures. Seizures can last from a few seconds to several minutes. They can have many symptoms, from convulsions and loss of consciousness to some that are not always recognized as seizures by the person experiencing them but by health care professionals: blank staring, lip smacking or jerking movements of arms and legs. One in 10 adults will have a seizure sometime during his or her life. Despite nearly ten new antiepileptic drugs being introduced over the past decade, 30 percent or close to one million people continue to have seizures even while taking two or more antiepileptic drugs.

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