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Marinus Pharmaceuticals Receives FDA Orphan Drug Designation for Ganaxolone IV to Treat Status Epilepticus

04/15/2016

RADNOR, Pa., April 15, 2016 (GLOBE NEWSWIRE) -- [Marinus Pharmaceuticals, Inc.](#) (Nasdaq:MRNS), a biopharmaceutical company dedicated to the development of innovative therapeutics to treat epilepsy and neuropsychiatric disorders, today announced that the U.S. Food and Drug Administration (FDA) has granted Orphan Drug Designation to the intravenous (IV) formulation of its CNS-selective GABA_A modulator, ganaxolone, for the treatment of status epilepticus. A Phase 1 clinical trial evaluating the safety, tolerability and pharmacokinetics of ganaxolone IV is expected to initiate in the first half of 2016.

"Status epilepticus is a life-threatening condition, associated with high mortality and if not treated immediately, can result in brain damage, cognitive impairment and death," remarked Christopher M. Cashman, Chief Executive Officer of Marinus Pharmaceuticals. "We are pleased to receive the Orphan Drug Designation for ganaxolone IV in this difficult to treat seizure disorder with limited treatment options."

Orphan Drug Designation is granted by the FDA Office of Orphan Products Development (OOPD) to novel drugs or biologics that treat a rare disease or condition affecting fewer than 200,000 patients in the U.S. The designation provides the drug developer with a seven-year period of U.S. marketing exclusivity, as well as tax credits for clinical research costs, the ability to apply for annual grant funding, clinical research trial design assistance and waiver of Prescription Drug User Fee Act (PDUFA) filing fees.

About Marinus Pharmaceuticals

Marinus Pharmaceuticals, Inc. is a biopharmaceutical company dedicated to the development of ganaxolone, which offers a new mechanism of action, demonstrated efficacy and safety and convenient dosing, to improve the lives of patients suffering from epilepsy and neuropsychiatric disorders. Ganaxolone is a CNS-selective GABA_A modulator that acts on a well-characterized target in the brain known to have both anti-seizure and anti-anxiety effects. Ganaxolone is being developed in three different dose forms (IV, capsule and liquid) intended to maximize therapeutic reach to adult and pediatric patient populations in both acute and chronic care settings. Ganaxolone IV is planned to enter clinical trials in 2016 and is being developed to treat status epilepticus. Ganaxolone IV is complemented by its oral dose forms, providing the potential for IV-to-oral continuation therapy for patients transitioning from acute care to outpatient settings. Ganaxolone capsule is being evaluated in a Phase 3 multi-national clinical trial as adjunctive treatment of focal onset seizures in adults. Ganaxolone capsule and liquid are being studied in orphan pediatric indications with comorbidities in seizures and behavior disorders — PCDH19 epilepsy and Fragile X Syndrome. For more information visit www.marinuspharma.com.

Forward-Looking Statements

[Skip to main content](#)

To the extent that statements contained in this press release are not descriptions of historical facts regarding Marinus, they are forward-looking statements reflecting the current beliefs and expectations of management made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of



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Securities and Exchange Commission.

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