Marinus Pharmaceuticals Doses First Subject in Phase 1 Clinical Trial for Ganaxolone IV

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RADNOR, Pa., June 22, 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 it has dosed the first subject in its Phase 1 clinical trial of ganaxolone IV, an intravenous (IV) formulation of Marinus' CNS-selective GABAA modulator, for the treatment of status epilepticus (SE). The study is designed to evaluate the safety, pharmacokinetics (PK), and pharmacodynamics (PD) of ganaxolone IV in healthy volunteers, with data anticipated in the second half of 2016.

Albena Patroneva, M.D., chief medical officer of Marinus Pharmaceuticals, commented, "Status epilepticus is a life-threatening medical emergency associated with high mortality and limited treatments. Typically, single or combination IV antiepileptic drugs are used in an attempt to break the seizures, however there are approximately 45,000 patients in the U.S. who do not respond to treatment and progress to established SE. Our preclinical research suggests ganaxolone IV could be a promising therapeutic in this difficult to treat seizure disorder, especially after first-line benzodiazepine treatment fails to halt the seizures. We look forward to reporting the results on this Phase 1 study later this year."

Christopher M. Cashman, chief executive officer of Marinus Pharmaceuticals, added, "Dosing the first subject with ganaxolone IV in SE is an important event for Marinus as we focus the development of ganaxolone on target patient populations where we believe there to be a strong mechanistic rationale for a therapeutic benefit with ganaxolone. Strategically, we believe that ganaxolone IV in combination with our convenient oral capsule and liquid formulations, has the potential to provide continuity of care for patients suffering from drug-resistant seizures in both acute and chronic care settings."

The Phase 1 study, which will be conducted at Duke University Medical Center, will include a dose escalation of a bolus dosage of ganaxolone IV and a bolus dose of ganaxolone IV, followed by a continuous infusion. The primary study objective is to evaluate the safety and PK of ganaxolone IV. The secondary study objectives include the PD effects of ganaxolone IV on electroencephalogram (EEG) parameters and ventilation, as well as the effect of ganaxolone IV on clinical sedation scores.

Marinus recently received Orphan Drug Designation for ganaxolone IV, providing the company with several benefits that could potentially shorten the timeline and reduce the costs of development.

About Marinus Pharmaceuticals

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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 GABAA modulator that acts on a well-characterized target in the brain known to have both anti-seizure and anti-anxiety effects. Ganaxolone is

in this press release include, among others, statements regarding our interpretation of preclinical studies, development plans for our product candidate, including the development of dose forms, the clinical trial testing schedule and milestones, interpretation of scientific basis for ganaxolone use, timing for availability and release of data, and the safety, potential efficacy and therapeutic potential of our product candidate. Forward-looking statements in this release involve substantial risks and uncertainties that could cause our clinical development programs, future results, performance or achievements to differ significantly from those expressed or implied by the forward-looking statements. Such risks and uncertainties include, among others, the uncertainties inherent in the conduct and outcome of future clinical trials, the timing of the clinical trials, enrollment in clinical trials, availability of data from ongoing clinical trials, expectations for regulatory approvals, and other matters, including the development of formulations of ganaxolone, that could affect the availability or commercial potential of our drug candidates. Marinus undertakes no obligation to update or revise any forward-looking statements. For a further description of the risks and uncertainties that could cause actual results to differ from those expressed in these forward-looking statements, as well as risks relating to the business of the Company in general, see filings Marinus has made with the Securities and Exchange Commission.

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