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Ganaxolone and Diazepam Administered Intravenously Synergistically Block Seizures in Animal Model of Status Epilepticus

Data Presented at Neuroscience 2016

RADNOR, Pa., Nov. 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, presented preclinical data showing that the combination of its CNS-selective $GABA_A$ modulator ganaxolone and diazepam administered intravenously (IV) produced a synergistic effect in blocking pilocarpine-induced seizures in a benzodiazepine refractory model of status epilepticus (SE). Marinus is developing ganaxolone IV for the treatment of status epilepticus, a life-threatening medical emergency associated with high mortality and limited treatment options. The data was presented during a poster presentation at Neuroscience 2016, the annual meeting of the Society for Neuroscience, which occurred November 12 — 16, 2016 in San Diego, CA.

The poster entitled, "Ganaxolone and diazepam administered IV produce a synergistic anti-epileptic effect in treatment refractory model of status epilepticus," was presented by Michael S. Saporito, Ph.D., a preclinical consultant to Marinus Pharmaceuticals. The data in the poster demonstrated that sub-therapeutic doses of diazepam and ganaxolone when administered in combination 15 minutes after onset of status epilepticus produced a partial or complete block of treatment-resistant status epilepticus in a rat model of SE, a clinically translatable model of this condition. Ganaxolone and diazepam plasma levels were measured alone and in combination and were identical, indicating that neither drug affected the pharmacokinetic disposition of the other. In addition, the study suggests that the synergistic enhancement of anti-epileptic activity occurred at the level of the $GABA_A$ receptor.

Albena Patroneva, M.D., chief medical officer at Marinus, commented, "The synergistic effect seen with the combination of ganaxolone and diazepam has the potential to deliver a meaningful combination for the treatment of status epilepticus, where more than 30% of patients become resistant to benzodiazepines. These results, along with previous preclinical studies, show that ganaxolone IV not only has potential as a standalone therapy in producing a complete block of status epilepticus, but could also be used in combination with benzodiazepines to produce a rapid break of continuous seizures. We look forward to advancing our ganaxolone IV into clinical studies for patients with status epilepticus."

Following positive Phase 1 results of ganaxolone IV in healthy volunteers, Marinus is preparing to commence its Phase 2 clinical study in patients with SE in 2017. Earlier this year, the U.S. Food and Drug Administration granted Orphan Drug Designation to ganaxolone IV for the treatment of SE.

About Ganaxolone

Ganaxolone is a CNS-selective $GABA_A$ modulator 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 acts on a well-characterized synaptic and extrasynaptic $GABA_A$ target known for its anti-seizure and anti-anxiety activity. Ganaxolone has been studied in more than 1,400 subjects, both pediatric and adult, at therapeutically relevant dose levels and treatment regimens for up to two years. In these studies, ganaxolone was generally safe and well tolerated, with the most commonly reported adverse events of somnolence, dizziness and fatigue.

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. Marinus is currently evaluating ganaxolone in orphan pediatric indications for the treatment of genetic seizure and behavior disorders, and preparing to initiate Phase 2 studies in status epilepticus, an orphan indication, and postpartum depression. For more information visit www.marinuspharma.com.

Forward-Looking Statements

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 1995. Words such as "may", "will", "expect", "anticipate", "estimate", "intend", "believe", and similar expressions (as well as other words or expressions referencing future events, conditions or circumstances) are intended to identify forward-looking statements. Examples of forward looking statements contained 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, the ability to complete enrollment in our clinical trials, interpretation of scientific basis for ganaxolone use, timing for availability and release of data, the safety, potential efficacy and therapeutic potential of our product candidate and our expectation regarding the sufficiency of our working capital. 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 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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