NEWS RELEASE

European Medicines Agency Grants Marinus Pharmaceuticals Accelerated Assessment of Ganaxolone for Treatment of CDKL5 Deficiency Disorder

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RADNOR, Pa.--(BUSINESS WIRE)-- **Marinus Pharmaceuticals, Inc**. (Nasdaq: MRNS), a pharmaceutical company dedicated to the development of innovative therapeutics to treat seizure disorders, today announced that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has granted its request for accelerated assessment of its lead product candidate, ganaxolone, for the treatment of seizures associated with CDKL5 deficiency disorder (CDD), a rare, genetic epilepsy.

“We believe this accelerated assessment by the EMA underscores ganaxolone’s potential to address areas of unmet medical need for patients and families afflicted by CDD,” said Kimberly McCormick, Pharm.D., Senior Vice President, Head of Regulatory Affairs at Marinus. “We plan to submit a marketing authorization application by the end of the third quarter and look forward to working with the EMA during its review of the application. If approved, our collaboration with Orion Corporation supports our efforts to bring ganaxolone to European markets as quickly as possible for CDD patients who may benefit.”

Accelerated assessment is granted by the CHMP when a medicinal product is expected to be of major public health interest and therapeutic innovation. Accelerated assessment potentially provides a reduced review timeline from 210 to 150 days once the marketing authorization application (MAA) is filed and validated, not counting clock stops when applicants are requested to provide additional information.

The MAA will be supported by data from the Phase 3 Marigold trial, a double-blind placebo-controlled trial in 101

patients. In the Marigold trial, patients treated with ganaxolone showed a 30.7% median reduction in 28-day major motor seizure frequency, compared to a 6.9% reduction for those receiving placebo, achieving the trial's primary endpoint (p=0.0036). Patients in the Marigold open label extension study treated with ganaxolone for at least 12 months (n=48) experienced a median 49.6% reduction in major motor seizure frequency. In this Phase 3 trial, ganaxolone was generally well-tolerated with a safety profile consistent with previous clinical trials, with the most frequent adverse event being somnolence.

The endorsement by the CHMP follows Marinus' recent submission of a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for the use of ganaxolone to treat seizures associated with CDD. An NDA filing notification letter from the FDA is expected before the end of Q3 2021.

About CDKL5 Deficiency Disorder

CDKL5 deficiency disorder (CDD) is a serious and rare genetic disorder that is caused by a mutation of the cyclin-dependent kinase-like 5 (CDKL5) gene, located on the X chromosome. CDD is characterized by early-onset, difficult-to-control seizures and severe neuro-developmental impairment. Currently, there are no therapies approved specifically for CDD.

About Ganaxolone

Ganaxolone, a positive allosteric modulator of GABAA receptors, is an investigational product being developed in intravenous and oral formulations intended to maximize therapeutic reach to adult and pediatric patient populations in both acute and chronic care settings. Ganaxolone exhibits anti-seizure and anti-anxiety activity via its effects on synaptic and extrasynaptic GABAA receptors. Ganaxolone has been studied in more than 1,800 pediatric and adult subjects across various indications at therapeutically relevant dose levels and in treatment regimens for up to more than two years.

About Marinus Pharmaceuticals

Marinus Pharmaceuticals, Inc. is a pharmaceutical company dedicated to the development of innovative therapeutics to treat seizure disorders. Ganaxolone is a positive allosteric modulator of GABAA receptors that acts on a well-characterized target in the brain known to have anti-seizure, antidepressant and anti-anxiety effects. Ganaxolone is being developed in IV and oral dose formulations intended to maximize therapeutic reach to adult and pediatric patient populations in both acute and chronic care settings. Marinus completed the first ever Phase 3 pivotal trial in children with CDKL5 deficiency disorder last year, is planning to conduct a Phase 3 trial in tuberous sclerosis complex, and a Phase 3 trial in refractory status epilepticus is ongoing. 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 expected clinical development plans, enrollment in our clinical trials, trial design, and regulatory communications and submissions for ganaxolone, and the timing thereof, including our plans to submit an MAA to the EMA by the end of Q3 2021; our expectation to receive an NDA filing notification letter from the FDA by the end of Q3 2021; our expectations and beliefs regarding the FDA with respect to our product candidates; and the potential safety and efficacy of ganaxolone, as well as its therapeutic potential in a number of indications.

Forward-looking statements in this press 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, uncertainties and delays relating to the design, enrollment, completion, and results of clinical trials; unanticipated costs and expenses; early clinical trials may not be indicative of the results in later clinical trials; clinical trial results may not support regulatory approval or further development in a specified indication or at all; actions or advice of regulatory agencies may affect the design, initiation, timing, continuation and/or progress of clinical trials or result in the need for additional clinical trials; our ability to obtain and maintain regulatory approval for our product candidate; our ability to obtain, maintain, protect and defend intellectual property for our product candidates; the potential negative impact of third party patents on our or our collaborators’ ability to commercialize ganaxolone; delays, interruptions or failures in the manufacture and supply of our product candidate; the size and growth potential of the markets for our product candidates, and our ability to service those markets; our cash and cash equivalents may not be sufficient to support our operating plan for as long as anticipated; our expectations, projections and estimates regarding expenses, future revenue, capital requirements, and the availability of and the need for additional financing; our ability to obtain additional funding to support our clinical development programs; our ability to develop sales and marketing capabilities, whether alone or with potential future collaborators; the rate and degree of market acceptance of our product candidates; the potential for Orion to breach its collaboration with us or terminate the collaboration agreement in accordance with its terms; the potential for Orion to recoup a percentage of the upfront fee depending on the additional pre-clinical testing expected to be completed in Q1 2022; the effect of the COVID-19 pandemic on our business, the medical community, regulators and the global economy; and the availability or potential availability of alternative products or treatments for conditions targeted by us that could affect the availability or commercial potential of our product candidate. This list is not exhaustive and these and other risks are described in our periodic reports, including the annual report on Form 10-K, quarterly reports on Form 10-Q and current reports on Form 8-K, filed with or furnished to the Securities and Exchange Commission. and available at **www.sec.gov**. Any forward-looking statements that we make in this press release

speak only as of the date of this press release. We assume no obligation to update forward-looking statements whether as a result of new information, future events or otherwise, after the date of this press release.

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