NEWS RELEASE

# Marinus Pharmaceuticals Announces Ganaxolone Approved in China as First Treatment for Seizures Associated with 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 China National Medical Products Administration (NMPA) has approved ganaxolone oral suspension for the treatment of epileptic seizures in patients two years of age and older with CDKL5 deficiency disorder (CDD).

In November 2022, Marinus and Tenacia Biotechnology entered into a **collaboration agreement** which granted Tenacia the right to develop and commercialize ganaxolone in Mainland China, Hong Kong, Macau and Taiwan in exchange for royalties and other payments associated with net sales and commercial and regulatory milestones.

“CDD is a severe and rapidly progressive neurodevelopmental disorder and before ganaxolone, there had been no treatments approved for this condition in China,” said Dr. Xiaoxiang Chen, Chief Executive Officer of Tenacia Biotechnology. “There is an urgent need to bring innovative new therapies to patients and families living with CDD, particularly as diagnosis rates continue to rise. We look forward to delivering the first and only treatment option for these patients in China.”

The approval is supported by data from Marinus’ Phase 3 Marigold trial in CDD, a double-blind placebo-controlled trial in 101 patients. 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 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 the Marigold trial, ganaxolone was generally well-tolerated and showed a safety profile consistent with previous clinical trials, with the most frequent

adverse event being somnolence.

“CDD brings unpredictability and increased healthcare needs and costs to patients and their families, and can significantly impact their quality of life,” said Kimberly McCormick, PharmD., Chief Regulatory and Quality Assurance Officer of Marinus. “The approval in China represents an important step forward for patients living with CDD and underscores our commitment to bringing innovative medicines to people living with rare genetic epilepsies across the globe. We’re grateful for the collaboration and support of Tenacia and regulatory authorities in China to bring this important new treatment option to patients with CDD.”

Ganaxolone has received regulatory approval in the U.S., European Union and China for appropriate patients with CDD. Under its collaboration agreements, Marinus supplies ganaxolone for all global markets.

## About ZTALMY® (ganaxolone) oral suspension

ZTALMY (ganaxolone) is a neuroactive steroid GABAA receptor modulator that acts on a well-characterized target in the brain known to have anti-seizure effects. It is a prescription medicine that has been approved by the U.S. Food and Drug Administration and the European Commission for appropriate patients with CDKL5 deficiency disorder.

**U.S. Prescribing Information** for ZTALMY® (ganaxolone) oral suspension CV.

**European Union Summary of Product Characteristics** for ZTALMY.

## About Marinus Pharmaceuticals

Marinus is a commercial-stage pharmaceutical company dedicated to the development of innovative therapeutics for seizure disorders. The Company first introduced FDA-approved prescription medication ZTALMY® (ganaxolone) oral suspension CV in the U.S. in 2022. For more information about Marinus visit **www.marinuspharma.com**.

## About Tenacia Biotechnology

Based in China and a portfolio company of Bain Capital, Tenacia is a clinical-stage biopharmaceutical company focused on developing and commercializing innovative treatments to address unmet medical needs of nervous system disorders. Tenacia is led by industry leaders with deep experience in life sciences and expertise in CNS, global and China-specific drug development and commercialization and demonstrated success in company formation. The company is advancing a portfolio of innovative, best-in-class therapies.

## 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 clinical development and commercialization plans and the timing thereof; our expectations regarding our collaboration with Tenacia and Tenacia's commercialization plans and the timing thereof; and other statements regarding our future operations, financial performance, financial position, prospects, objectives and other future events.

Forward-looking statements in this press release involve substantial risks and uncertainties that could cause our clinical development and commercialization 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, unexpected results or delays in the commercialization of ZTALMY; unexpected market acceptance, payor coverage or future prescriptions and revenue generated by ZTALMY; unfavorable pricing regulations, third-party reimbursement practices or healthcare reform initiatives; unexpected actions by the FDA or other regulatory agencies with respect to our products; competitive conditions and unexpected adverse events or patient outcomes from being treated with ZTALMY, uncertainties and delays relating to the design, enrollment, completion, and results of clinical trials; unanticipated costs and expenses; the varying interpretation of clinical data; our ability to comply with the FDA's requirement for additional post-marketing studies in the required time frames; the timing of regulatory filings for our other product candidates; the potential that regulatory authorities, including the FDA and EMA, may not grant or may delay approval for our product candidates; 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 the FDA or EMA 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 develop new formulations of ganaxolone or prodrugs; 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 ability to continue as a going concern; 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 and commercial programs; the potential for our ex-U.S. partners to breach their obligations under their respective agreements with us or terminate such agreements in accordance with their respective terms; the risk that drug product quality requirements may not support continued clinical investigation of our product candidates and result in delays or termination of such clinical studies and product approvals; 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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