NEWS RELEASE

Marinus Pharmaceuticals Provides Update on the Phase 3 RAISE Trial and Reports Preliminary First Quarter 2024 Financial Results

4/15/2024

Trial did not meet pre-defined stopping criteria at the interim analysis; Marinus has completed RAISE enrollment at approximately 100 patients with topline results expected summer 2024

Future development of IV ganaxolone in refractory status epilepticus to be assessed following review of the final RAISE results

Enrollment in the TrustTSC trial expected to complete mid-May with topline data on track for the first half of Q4 2024

Cost reduction activities to extend cash runway are under review and expected to be implemented Q2 2024

ZTALMY® (ganaxolone) Q1 2024 preliminary net product revenue of between $7.4 and $7.6 million; preliminary unaudited cash, cash equivalents and short-term investments of $113.3 million as of March 31, 2024

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 an independent Data Monitoring Committee (DMC) has recommended continuing the pivotal Phase 3 RAISE trial evaluating intravenous (IV) ganaxolone for the treatment of refractory status epilepticus (RSE) following an interim analysis.

Marinus has decided to complete enrollment in the RAISE trial at approximately 100 patients with topline results

expected in the summer of 2024. Those results will be used to determine whether to continue development of IV ganaxolone. Marinus remains blinded to the RAISE trial data.

“While we are disappointed that RAISE did not meet the early stopping criteria, we will only be able to determine the trial’s outcome once we unblind and analyze the full data set,” said Scott Braunstein, M.D., Chairman and Chief Executive Officer of Marinus. “We will also be evaluating potential cost-saving strategies to provide the strongest capital position as we approach enrollment completion in the global Phase 3 TrustTSC trial in tuberous sclerosis complex.”

Ganaxolone development in the RAISE trial is being supported in part by the Department of Health and Human Services; Administration for Strategic Preparedness and Response; Biomedical Advanced Research and Development Authority (BARDA) under contract number 75A50120C00159.

General Business and Financial Update

Marinus expects to complete enrollment in the Phase 3 TrustTSC trial of ZTALMY® (ganaxolone) oral suspension CV with approximately 130 patients in mid-May 2024. The Company expects topline results early in the fourth quarter of 2024 and anticipates filing a supplemental New Drug Application to the U.S. Food and Drug Administration in the first half of 2025 with a request for priority review.

Marinus also continues to develop a second-generation ganaxolone formulation intended to provide improved pharmacodynamic and pharmacokinetic profiles that could improve safety, efficacy and tolerability and enable less frequent dosing.

The Company continues the successful U.S. commercial launch of ZTALMY resulting in preliminary unaudited net product revenue of between $7.4 and $7.6 million for the first quarter of 2024. Marinus estimates preliminary unaudited cash, cash equivalents, and short-term investments of $113.3 million as of March 31, 2024. Cost reduction activities to extend the cash runway beyond the fourth quarter of 2024 are under review and are expected to be implemented in the current quarter.

The preliminary first quarter 2024 net product revenue results and cash, cash equivalents, and short-term investments included in this release were calculated prior to the completion of a review by the Company’s independent registered public accounting firm and are therefore subject to adjustment.

About Status Epilepticus

Status epilepticus (SE) is a life-threatening condition resulting from either the failure of the mechanisms responsible

for seizure termination or from the initiation of mechanisms which lead to abnormally prolonged seizures.1 SE is the one of the most common neurological emergencies in the U.S., affecting up to 150,000 patients each year, and is associated with substantial morbidity, mortality, and healthcare costs.2,3,4 Patients who do not respond to 1st- and 2nd-line treatments (benzodiazepines and intravenous antiseizure medications) are considered to have refractory SE (RSE).4,5

About Intravenous (IV) Ganaxolone

Ganaxolone is a neuroactive steroid that works by modulating both synaptic and extrasynaptic GABAA receptors via a unique binding site to potentiate two types of inhibitory signaling.6 IV ganaxolone has pharmacokinetic and pharmacodynamic properties well-suited for the treatment of status epilepticus, with rapid and sustained SE cessation observed in pre-clinical and clinical studies.7,8,9 IV ganaxolone has received orphan drug designation from the U.S. Food and Drug Administration for the potential treatment of status epilepticus.

About the RAISE Trial

The RAISE (Randomized Therapy in Status Epilepticus) trial (**NCT04391569**) is a Phase 3 double-blind, randomized, placebo-controlled clinical trial to evaluate the safety and efficacy of IV ganaxolone in patients with refractory status epilepticus. The RAISE protocol provides for an independent data monitoring committee to conduct an unblinded interim analysis when two-thirds of participants, or approximately 82 patients, have completed the trial.

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 and continues to invest in the potential of ganaxolone in IV and oral formulations to maximize therapeutic reach for adult and pediatric patients in acute and chronic care settings. For more information about Marinus visit **www.marinuspharma.com**.

1 Trinka E, et al. Epilepsia. 2015;56(10):1515-1523.

2 Betjemann JP, Lowenstein DH. Lancet Neurol. 2015;14(6):615-24.

3 Guterman EL et al. JAMA Neurol. 2021;78(5):588-95.

4 Glauser T et al. Epilepsy Curr. 2016;16:48-61.

5 Brophy GM et al. Neurocrit Care. 2012;17:3-23.

6 Reddy, D. S. Front Cell Neurosci 7, 115 (2013).

7 Zolkowska D et al. Epilepsia. 59(suppl 2):220-227.

8 Gasior M et al. Clin Pharmacol Drug Dev 13: 248-25.

9 Vaitkevicius H et al. Epilepsia 2022; 63(9): 2381-2391.

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 the expectation that the results from the RAISE trial will be used to determine whether to continue development of IV ganaxolone; our plans to evaluate potential cost-saving strategies to provide the strongest capital position and extend cash runway, and the implementation and related timing thereof; our belief that a second-generation ganaxolone formulation may provide improved pharmacodynamic and pharmacokinetic profiles that could improve safety, efficacy and tolerability and enable less frequent dosing; the intent to explore new clinical programs for ZTALMY in other refractory epilepsies, and the timing thereof; the potential benefits ZTALMY will provide for physicians and patients; statements regarding our expected clinical development plans, enrollment in our clinical trials, results from our clinical trials, regulatory communications and submissions for ganaxolone, and the timing thereof; the safety and efficacy of ganaxolone, as well as its therapeutic potential in a number of indications; 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 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; 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 its 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 its 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.

Investors

Jim DeNike

Senior Director, Investor Relations

Marinus Pharmaceuticals, Inc.

jdenike@marinuspharma.com

Media

Molly Cameron

Director, Corporate Communications & Investor Relations

Marinus Pharmaceuticals, Inc.

mcameron@marinuspharma.com

Source: Marinus Pharmaceuticals