Relmada Therapeutics Expands R&D Team, Appoints Paolo Manfredi, M.D., as Acting Chief Scientific Officer, Marco Pappagallo, M.D., as Acting Chief Medical Officer and Updates R&D Milestones

Description

NEW YORK, Oct. 27, 2020 /PRNewswire/ — Relmada Therapeutics, Inc. (Nasdaq: RLMD), a clinical-stage company developing novel therapies for the treatment of central nervous system (CNS) diseases, today announced the expansion of its leadership team with the appointments of Paolo Manfredi, M.D., as Acting Chief Scientific Officer and Marco Pappagallo, M.D., as Acting Chief Medical Officer. The Company also provided an update of upcoming milestones for the REL-1017 program.

Relmada Therapeutics Corporate Logo

Dr. Manfredi has been the co-founder of Medeor, Inc. (now merged into Relmada), for which he also served as Scientific Director and co-inventor of REL-1017. Prior to this, Dr. Manfredi was an Assistant Professor in Neurology and Neuroscience at the Weill Medical College of Cornell University and served as the Fellowship Director of the Pain and Palliative Care Program at Memorial Sloan Kettering Cancer Center. Dr. Manfredi earned his Doctor of Medicine at the University of Genoa, Italy, completed his residency in neurology at Albert Einstein College of Medicine and completed several postdoctoral training fellowships, including a pain management fellowship at Massachusetts General Hospital and Harvard University.

Dr. Pappagallo most recently served as Chief Medical Officer at CerSci Therapeutics, a privately-held biotech company focused on developing pain therapeutics that was recently acquired by ACADIA Pharmaceuticals. Prior to this, he held the role of Medical Expert-in-Residence and Executive Director of Medical Intelligence at Grünenthal – USA. Dr. Pappagallo previously served as the co-founder and Chief Medical Officer of NovaPharm Therapeutics. Dr. Pappagallo served in a number of senior roles at leading medical institutions, including as the Director of Chronic Pain in the Department of Pain and Palliative Care at Beth Israel Medical Center and Professor and Director of Pain Research in the Department of Anesthesiology at Mount Sinai Medical Center. Dr. Pappagallo completed his medical school and post-graduate training in neurosurgery at the University of Rome, Italy. Subsequently, he completed his neurology residency training at the State University of New York at Stony Brook and was a clinical and research fellow in pain medicine at John Hopkins University.

Relmada also provided an R&D milestone update, as the company continues to be on track to start its first pivotal Phase III trial of REL-1017 for the adjunctive treatment of major depressive disorder (MDD) in the fourth quarter of 2020. Also, this quarter, the company expects to begin its human abuse potential studies of REL-1017. Other anticipated milestones for REL-1017 in 2021 include:

- 1H21 – Start of second pivotal Phase III adjunctive MDD trial
- 1H21 – Start of Phase II monotherapy MDD trial

- 2Q21 – Results of human abuse potential studies
- 4Q21 – Results of Phase II monotherapy MDD trial
- 1H22 – Results of Phase III adjunctive MDD trials

“We are delighted to welcome Dr. Manfredi and Dr. Pappagallo to Relmada’ s leadership team. Dr. Manfredi was the co-founder of Medeor, Inc., now merged into Relmada. As a co-inventor of our core technology, Dr. Manfredi’s deep insight and expertise will continue to be invaluable in the further clinical development of our lead product candidate, REL-1017,” said Sergio Traversa, Chief Executive Officer of Relmada. “Dr. Pappagallo brings over 30 years of medical expertise in neurology medicine. With his significant experience directing clinical programs and passion for addressing significant medical unmet needs, Dr. Pappagallo will be instrumental in shaping Relmada’ s future clinical development strategy and execution. We look forward to the significant contributions of both of these world-renowned medical experts. We are also quite excited to provide our milestone update, which highlights our team’s robust progress, as we continue to advance REL-1017’s late-stage development.”

“I am delighted to expand my commitment to Relmada to oversee its research programs as Acting Chief Scientific Officer and lead the scientific development of REL-1017, a compound with which I am extremely familiar and I look forward to advancing this innovative treatment,” said Dr. Manfredi.

Dr. Pappagallo commented, “I am excited about joining a team focused on addressing diseases of the CNS with innovative approaches, and most importantly to help the millions of people who continue to need new options for the treatment of MDD. I look forward to leading the next and last phase of clinical development of REL-1017, as an adjunctive as well as front line monotherapy treatment of MDD, as we progress our development program.”

About REL-1017

REL-1017, a novel NMDA receptor (NMDAR) channel blocker that preferentially targets hyperactive channels while maintaining physiological glutamatergic neurotransmission, is entering late-stage studies as an adjunctive treatment for MDD in adults. In addition to safety and efficacy, our clinical program for REL-1017 will evaluate its potential as the first rapid-acting, oral, once-daily antidepressant treatment. In a Phase 2 trial, REL-1017 demonstrated rapid onset and sustained antidepressant effects with statistically significant improvements as compared to placebo on efficacy measures. The Phase 2 study also confirmed the favorable safety and tolerability profile of REL-1017 observed in previously completed Phase 1 studies. In April 2017, the FDA granted Fast Track designation for REL-1017 for the adjunctive treatment of major depressive disorder.

About Relmada Therapeutics, Inc.

Relmada Therapeutics is a late-stage pharmaceutical company addressing diseases of the central nervous system (CNS), with a focus on major depressive disorder (MDD). Our experienced and dedicated team is committed to making a difference in the lives of patients and their families. Relmada’ s lead program, REL-1017, is a novel NMDA receptor (NMDAR) channel blocker that preferentially targets hyperactive channels while maintaining physiological glutamatergic neurotransmission, and is entering late-stage studies as an adjunctive treatment for MDD in adults.

Forward-Looking Statements
The Private Securities Litigation Reform Act of 1995 provides a safe harbor for forward-looking statements made by us or on our behalf. This press release contains statements which constitute “forward-looking statements” within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934, including but not limited to statements regarding the expected use of the proceeds from the offering. Any statement that is not historical in nature is a forward-looking statement and may be identified by the use of words and phrases such as “expects,” “anticipates,” “believes,” “will,” “will likely result,” “will continue,” “plans to,” “potential,” “promising,” and similar expressions. These statements are based on management’s current expectations and beliefs and are subject to a number of risks, uncertainties and assumptions that could cause actual results to differ materially from those described in the forward-looking statements, including the risk factors described under the heading “Risk Factors” set forth in the Company’s reports filed with the SEC from time to time. No forward-looking statement can be guaranteed, and actual results may differ materially from those projected. Relmada undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events, or otherwise. Readers are cautioned that it is not possible to predict or identify all the risks, uncertainties and other factors that may affect future results and that the risks described herein should not be a complete list.

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