

Relmada Therapeutics Solidifies its R&D Leadership Team with the Appointment of Marc de Somer, MD, MBA, ScD, MPH, MSc, as Senior Vice President, Clinical Development and Safety

Description

NEW YORK, March 31, 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 appointment of Marc de Somer, MD, MBA, ScD, MPH, MSc, as Senior Vice President, Clinical Development and Safety. Dr. de Somer will oversee Clinical Development and Safety at Relmada. He has over 30 years of experience in global clinical development strategy, design, execution, and evaluation.

[Relmada Therapeutics Corporate Logo](#)

Dr. de Somer joins Relmada from Prilenia Therapeutics, a privately-held, clinical-stage biotechnology company focused on developing treatments for neurodegenerative and neurodevelopmental disorders, where he served as Chief Medical Officer (CMO). He was responsible for clinical R&D strategy, tactical leadership and management from translational medicine to full development and regulatory interactions. Previously, Dr. de Somer served as VP of Clinical R&D & Medical Affairs at leading CNS-focused biotechnology companies, Voyager Therapeutics and Alkermes, and also was VP Neurology at PPD Biotech, a prominent clinical research organization. In these roles, he was responsible for numerous pre-IND to NDA interactions with U.S., European and Japanese regulators. During the course of his career, Dr. de Somer's clinical leadership has resulted in global regulatory approvals of several drugs, including Exelon® in Alzheimer's dementia, Comtan® and Stalevo® in Parkinson's disease, Differin® in dermatology, Artistada® in schizophrenia, and he is a co-inventor of apomorphine sublingual film (acquired by Sunovion and currently undergoing NDA review) in late-stage Parkinson's disease, as well as Miacalcin® in post-menopausal osteoporosis and Sandimmune® Neoral® in organ transplantation. Earlier in his career, Dr. de Somer co-founded three venture capital-backed clinical-stage neuroscience start-ups where he served as CMO and EVP R&D, with two successful mergers and acquisitions (M&A) exits. Prior to this, he had leadership responsibilities in Europe, UK and U.S. of clinical line functions and projects at Sandoz/Novartis Pharmaceuticals.

Dr. de Somer earned an MD from Brussels Free University, Belgium, a doctorate from the Institute of Tropical Medicine in Antwerp, Belgium, an MSc in biostatistics (a joint program of Harvard School of Public Health, Imperial College London, and Leuven/Hasselt University, Belgium), and an executive MBA from Columbia University Business School. Additionally, he has an MPH, a postgraduate degree in epidemiology and an MSc in pharmaceutical medicine.

"Marc has led the development of multiple marketed CNS drugs during his prominent career," said Thomas Wessel, Head of R&D at Relmada. "We are thrilled to have someone with his vast knowledge of

the CNS field, extensive clinical trial management experience and substantial regulatory expertise join our team. We are now planning for our first pivotal Phase 3 study of REL-1017 as an adjunctive treatment in patients with major depression to start in the second half of this year, and Marc's contributions to study design and execution will be critical."

"I am very excited to focus on maximizing our probability of success, defeating placebo response and excessive noise to demonstrate the true therapeutic signal with the necessary accuracy, precision and replicability. I look forward to working with the Relmada team, as we effectively conduct clinical trials to provide the highest quality of information and therapeutic value for patients, prescribers, payers and shareholders," said Dr. de Somer. "I look forward to contributing to de-risking development of REL-1017 in MDD, and additional indications and programs, as we build our pipeline and team."

About dextromethadone (REL 1017)

Relmada is currently developing dextromethadone as a rapidly acting oral agent for the treatment of depression. Working as an NMDA receptor antagonist and on the same binding site as ketamine but having shown no ketamine psychotomimetics side effects, dextromethadone is fundamentally differentiated from all currently FDA-approved antidepressants, as well as all atypical antipsychotics used adjunctively. In April 2017, the FDA granted Fast Track designation for dextromethadone for the adjunctive treatment of major depressive disorder.

About Relmada Therapeutics, Inc.

Relmada Therapeutics is a clinical-stage, publicly traded biotechnology company developing novel medicines to address areas of high unmet medical need in the treatment of central nervous system (CNS) diseases. Relmada's lead program, dextromethadone (REL-1017), is an N-methyl-D-aspartate (NMDA) receptor antagonist in development for the treatment of depression. NMDA receptor antagonists may have utility in the treatment of a range of psychiatric and neurological disorders associated with a variety of cognitive, neurological and behavioral symptoms.

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" 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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