

Relmada Therapeutics Enhances Senior Leadership Team with Appointment of Brian A. Walter, Ph.D., as Vice President of Regulatory Affairs

Description

NEW YORK, April 28, 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 Brian A. Walter, Ph.D., as Vice President of Regulatory Affairs. Dr. Walter will provide oversight for all U.S. and international regulatory strategy and operations. He has more than 30 years of experience in the biopharmaceutical industry, including 20 years in global regulatory affairs leading small molecule products and biologics, including antibodies and gene therapies, through the regulatory process from early development to approval.

[Relmada Therapeutics Corporate Logo_](#)

Dr. Walter joins Relmada from REGENXBIO Inc., where he most recently served as Vice President of Regulatory Affairs, responsible for the global regulatory strategy, operations, pharmacovigilance, and medical writing for the company's portfolio of AAV-based gene therapy development candidates.

Previously, from 2014 to 2018, Dr. Walter was Executive Director of Regulatory Affairs at Regeneron Pharmaceuticals, where he led and managed the regulatory affair liaison group for metabolic & endocrine, infectious diseases, immunology, drug-device combinations, and companion diagnostics for development and marketed products. From 2006 to 2014, Dr. Walter was Vice President, Regulatory Affairs, for Acorda Therapeutics, where he established and led the regulatory affairs department from pre-IPO to approval of the company's first marketed product. From 1994 to 2006, Dr. Walter served in multiple roles at Boehringer Ingelheim Pharmaceuticals, most recently as Senior Associate Director, Drug Regulatory Affairs, Cardiovascular, CNS and General Drugs Section. From 1989 to 1994, he was Group Head, Human Metabolism, Clinical Pharmacokinetics and Disposition Department, at CIBA-GEIGY Corporation. From 1988 to 1989, Dr. Walter was a chemist in the Biochemistry Department of BAYER Corporation, Agricultural division.

Dr. Walter earned his B.S. in biology from Denison University in Granville, Ohio, and his Ph.D. in toxicology and drug metabolism from the University of Kentucky College of Pharmacy.

"I am delighted to join the Relmada R&D team and look forward to advance REL-1017, an orally delivered anti-depressant with a potentially unique rapid-onset of action and sustained antidepressant effect for the treatment of patients with a major depressive disorder. REL-1071 has been designated by FDA as a Fast-Track drug, and, if approved, will fulfill an unmet medical need for patients with a serious condition," said Dr. Walter. "It is an exciting time for the Company, and I look forward to working with the Relmada team to develop regulatory strategies to advance this innovative treatment for patients and their families."

"Dr. Walter has an impressive track record in regulatory affairs. We are thrilled to have Brian join the growing Relmada R&D team at this juncture, as we plan for our phase 3 program of REL-1017 and

consider regulatory strategies in the EU, Japan and the rest of the world,” said Thomas Wessel, Head of Research and Development at Relmada.

“Brian is a highly experienced regulatory affairs professional,” said Sergio Traversa, Chief Executive Officer of Relmada. “He has led the interactions with regulatory agencies globally around a multitude of development and marketed products. We look forward to leveraging Brian’s broad expertise as we discuss the planning of our pivotal Phase 3 program of REL-1017 as an adjunctive treatment in patients with major depression with the U.S. Food and Drug Administration and other regulatory agencies around the world.”

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.

Investor Contact:

Tim McCarthy
LifeSci Advisors
212-915-2564
tim@lifesciadvisors.com

For Media Inquiries:
FischTank Marketing and PR
relmada@fischtankpr.com

 View original content to download multimedia: <http://www.prnewswire.com/news-releases/relmada-therapeutics-enhances-senior-leadership-team-with-appointment-of-brian-a-walter-phd-as-vice-president-of-regulatory-affairs-301048136.html>

SOURCE Relmada Therapeutics, Inc.

Released April 28, 2020

Date Created

2020/04/28