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Relmada Therapeutics Announces Notice of Allowance for Patent in Canada Covering REL-1017 for Treatment of Psychiatric Symptoms

Patent Further Expands Company's Intellectual Property Protection for REL-1017 a Novel NMDA Receptor Antagonist, in a Major Global Market

NEW YORK, June 23, 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 receipt of a Notice of Allowance from the Canadian Intellectual Property Office for Relmada's patent application number, 2,893,238, titled, "d-Methadone for the Treatment of Psychiatric Symptoms." The patent that will issue from this allowed application provides broad coverage in Canada for REL-1017 (d-methadone, dextromethadone,), a novel N-methyl-D-aspartate (NMDA) receptor antagonist, for the treatment of symptoms associated with a wide range of psychological and psychiatric disorders, including depression, anxiety, fatigue, and mood instability.



"This patent, which has previously been granted in the U.S., EU, Australia, China, Hong Kong, Mexico, and South Korea, advances our objective of further strengthening our intellectual property portfolio in multiple key markets around the world," said Sergio Traversa, CEO of Relmada Therapeutics. "Canada represents a significant market opportunity for Relmada, as published research indicates that the 12 months' prevalence rate of major depressive disorder (MDD) in Canada was 4.7%, and the lifetime prevalence rate was 11.2%¹. We look forward to initiating our Phase 3 program for REL-1017 for the adjunctive treatment of MDD in the fourth quarter of this year."

Relmada recently completed an End-of-Phase 2 meeting with the U.S. Food and Drug Administration (FDA) on its development program of REL-1017 for the adjunctive treatment of MDD patients. Based on the FDA feedback, the Company can proceed into Phase 3 without conducting additional clinical studies, and the FDA and Relmada are aligned on all key aspects of the planned Phase 3 program.

About REL-1017 (dextromethadone)

REL-1017 is a non-competitive N-methyl-D-aspartate Receptor (NMDAR) antagonist with the potential to be the first oral single agent NMDAR antagonist approved for the adjunctive

treatment of MDD. 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 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, REL-1017 (dextromethadone) 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," "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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¹ Knoll, A. D., & MacLennan, R. N. (2017). Prevalence and correlates of depression in

Canada: Findings from the Canadian Community Health Survey. *Canadian Psychology/Psychologie Canadienne*, 58(2), 116–123.

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