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Relmada Therapeutics Provides Regulatory and Development Updates on Ongoing Late-Stage Clinical Program for REL-1017 for Treatment of Major Depressive Disorder

Relmada is actively enrolling patients in RELIANCE III, a Monotherapy Registrational Phase 3 Study

FDA Confirms Relmada Not Required to Conduct Two-Year Carcinogenicity Study and TQT Cardiac Study in Humans to Support Potential Regulatory Approval Submissions for REL-1017

CORAL GABLES, Fla., Oct. 4, 2021 /PRNewswire/ -- Relmada Therapeutics, Inc. (NASDAQ: RLMD), a late-stage biotechnology company addressing diseases of the central nervous system (CNS), today provided regulatory and development updates regarding its ongoing late-stage clinical program for REL-1017 in major depressive disorder (MDD).

RELIANCE III, the new ongoing monotherapy trial, aims to randomize 364 patients and it is expected to be completed in the second quarter of 2022.

In addition, in order to support potential regulatory submissions seeking approval for REL-1017 as monotherapy and adjunctive treatment, the FDA confirmed that, based on what is known at this time, Relmada will not be required to conduct a two-year carcinogenicity study of esmethadone (REL-1017), as sufficient pre-clinical safety data have been generated to date. The FDA also confirmed that Relmada does not need to conduct a TQT cardiac study in humans to support cardiac safety in potential regulatory submissions for REL-1017, as the data provided so far and the data generated by the Phase 3 program will be adequate to evaluate the cardiac safety profile of REL-1017.

"We are pleased that the RELIANCE III monotherapy registrational Phase 3 trial is up and running," said Dr. Paolo Manfredi, CSO of Relmada Therapeutics. "We believe that this advancement is indicative of the significant potential of REL-1017 to treat MDD. Importantly,

conducting RELIANCE III as a Phase 3 study may meaningfully reduce the time to potential approval for REL-1017 as MDD monotherapy. We are continuing to actively enroll patients into RELIANCE I and RELIANCE II, our MDD adjunctive treatment pivotal trials, as well as into the new RELIANCE III monotherapy study. Meanwhile, RELIANCE OLE, the open label extension safety study, which is enrolling patients from RELIANCE I, II AND III, as well as de novo patients, is progressing steadily."

About REL-1017

REL-1017, a new chemical entity (NCE) and novel NMDA receptor (NMDAR) channel blocker that preferentially targets hyperactive channels while maintaining physiological glutamatergic neurotransmission, is currently in late-stage development for the treatment of MDD. The ongoing RELIANCE Clinical Research Program is designed to evaluate the potential for REL-1017 as the first rapid-acting, oral, once-daily antidepressant treatment. In a Phase 2 trial, REL-1017 demonstrated rapid, robust and sustained antidepressant effects with statistically significant improvements compared to placebo in all tested measures of depression. The Phase 2 study also confirmed the favorable safety, tolerability and pharmacokinetics profile of REL-1017 observed in previously completed Phase 1 studies.

About Relmada Therapeutics, Inc.

Relmada Therapeutics is a late-stage biotechnology company addressing diseases of the central nervous system (CNS), with a focus on major depressive disorder (MDD). Relmada's 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 new chemical entity (NCE) and novel NMDA receptor (NMDAR) channel blocker that preferentially targets hyperactive channels while maintaining physiological glutamatergic neurotransmission. REL-1017 has entered late-stage development as an adjunctive treatment for MDD in adults. In addition, Relmada is advancing a clinical-stage program in neurodegenerative diseases based on psilocybin and select derivative molecules. Learn more at www.relmada.com.

Forward-Looking Statements

The Private Securities Litigation Reform Act of 1995 provides a safe harbor for forward-looking statements made by Relmada or on its 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 Relmada's plans to develop REL-1017; and expectations related to trials evaluating REL-1017 and potential regulatory approval of REL-1017, including those related to feedback from the FDA. 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 Relmada'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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