Relmada Therapeutics Announces Top-Line Results of Study Evaluating REL-1017 vs Oxycodone for Abuse Potential

Description

– All tested doses of REL-1017, including the maximum tolerated dose, showed a highly statistically significant difference in abuse potential vs. oxycodone with p-values <0.001

– Company to host conference call at 8:30 AM Eastern Time today July 27, 2021

NEW YORK, July 27, 2021 /PRNewswire/ — Relmada Therapeutics, Inc. (Nasdaq: RLMD), a late-stage biotechnology company addressing diseases of the central nervous system (CNS), announced today top-line results of the human abuse potential (HAP) study with REL-1017, a novel NMDA receptor (NMDAR) channel blocker and the company's lead candidate in Phase 3 development for the treatment major depressive disorder (MDD).

Relmada Therapeutics Corporate Logo (PRNewsFoto/Relmada Therapeutics, Inc.)

Top-line results showed that all three doses of REL-1017 (25 mg, 75 mg and 150 mg, the therapeutic, supratherapeutic and maximum tolerated doses, respectively) tested in recreational opioid users, demonstrated a highly statistically significant difference vs. the active control drug, oxycodone 40 mg. The study's primary endpoint was a measure of "likability" with the subjects rating the maximum effect (or Emax) for Drug Liking "at the moment", using a 1=100 bipolar rating scale (known as a visual analog scale or VAS), with 100 as the highest likability, 50 as neutral (placebo-like), and 0 the highest dislike. Results are summarized in the table below.

	Placebo	**REL-1017 25 mg**	**REL-1017 75 mg**	**REL-1017 150 mg**	**Oxycodone 40 mg**
Mean Emax for Drug Liking	51.7	53.0	58.2	64.9	85.0
P-value for Difference vs. oxycodone 40 mg	<0.001	<0.001	<0.001	<0.001	–

"These highly statistically significant data clearly demonstrate a very meaningful difference between REL-1017 and oxycodone at all three tested doses" said Sergio Traversa, CEO of Relmada Therapeutics.

"These results, along with previously published literature, confirm the lack of opioid effects of REL-1017. We look forward to the continued clinical development of REL-1017 as a novel, safe and rapidly effective treatment for MDD."

"We are pleased with the results of this confirmatory study, which was designed in line with U.S. Food and Drug Administration (FDA) guidance," said Dr. Paolo Manfredi, Chief Scientific Officer of Relmada. "Importantly, these data are consistent with our development program and confirm the extensive body of literature indicating the lack of abuse potential of REL-1017. Patients suffering from depression are in great need of new safe and rapidly effective treatments. These results strongly support the ongoing REL-1017 late-stage development program."

"These results are consistent with HAP results we have seen for other drugs that affect the CNS, and which have been Scheduled at Classes IV or V, or even unscheduled, during the assessment and review period." said Jack Henningfield, Ph.D., Vice President, Research, Health Policy, and Abuse Liability at Pinney Associates and former Chief of the Clinical Pharmacology Research Branch and the Abuse Potential and Biology of Dependence Assessment Section of the National Institute on Drug Abuse (NIDA). "These data do not provide evidence for abuse potential."

Conference Call and Webcast Information

Relmada will host a conference call and webcast presentation today, July 27, 2021 at 8:30 AM Eastern Time to discuss the study results, which can be accessed with the information below:

Tuesday, July 27 at 8:30 AM ET

Domestic: 877-407-0792

International: 201-689-8263

Conference ID: 13721997

Webcast: http://public.viavid.com/index.php?id=145999

The subsequent archived recording will be available on the Investors section of the Relmada website at www.relmada.com.

Background

REL-1017 (which is also known as esmethadone, dextromethadone, or d-methadone), is the opioid-inactive, dextro- or right-side isomer of racemic methadone. Prior preclinical and clinical findings have indicated that the dextro-isomer REL-1017 lacks the addiction liability and respiratory depressant effects of its parent molecule. In contrast, levomethadone, the left-side isomer, is an opioid agonist and is entirely responsible for the analgesic activity of the parent molecule.[1]

Human Abuse Potential (HAP) studies are conducted to evaluate the likelihood that a medicine affecting the central nervous system may be abused by patients or the general public. The study comparing REL-1017 to oxycodone is the first of two clinical trials to assess abuse potential per FDA guidance as part of the planned REL-1017 NDA for the treatment of MDD.

The scheduling of a drug depends on the analysis of several parameters (receptor studies, animal studies, human studies, history of abuse). These parameters are generally referred to as the “eight factor analysis”. All tested parameters suggest a lack of any meaningful abuse potential for REL-1017 and are fully aligned with the 2019 DEA statement on methadone.[1]

About The Human Abuse Potential Study for REL-1017 vs. Oxycodone

The study was a single-dose, Phase 1, randomized, double-blind, double-dummy, active- and placebo-controlled, five-way crossover study to assess the abuse potential of REL-1017 relative to oxycodone and placebo in healthy experienced recreational drug users. Oxycodone, the active control, was administered at the dose of 40 mg, a standard dose in HAP studies. A total of 50 subjects were enrolled and 44 fulfilled criteria for the predefined statistical analysis.

Once available, the full data set and detailed results will be submitted to the FDA and for presentation at future scientific conferences and publication in peer-reviewed journals.

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 robust, rapid and sustained antidepressant effects with statistically significant improvements compared to placebo. The Phase 2 study also confirmed the favorable pharmacokinetic, safety and tolerability 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). 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 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. 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 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.

Investor Contact:
Tim McCarthy
LifeSci Advisors
917-679-9282
tim@lifesciadvisors.com

Media Inquiries:
FischTank PR
Relmada@FischTankPR.com

Reference:

1. DEA: Diversion Control Division. December 2019. Accessed May 2020. https://www.deadiversion.usdoj.gov/drug_chem_info/methadone/methadone.pdf

View original content to download multimedia:https://www.prnewswire.com/news-releases/relmada-therapeutics-announces-top-line-results-of-study-evaluating-rel-1017-vs-oxycodone-for-abuse-potential-301341996.html

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