

Relmada Therapeutics Announces Additional Information Regarding Positive Topline Results for Proof-of-Concept Study with BuTab

Description

Absolute Bioavailability of BuTab Relative to Intravenous Administration Exceeded Published Data with Non-Modified Buprenorphine; Compares Favorably with Currently Marketed Transdermal Patch

Conference Call and Webcast Scheduled at 8:30 a.m. ET today, December 10, 2015

NEW YORK, Dec. 10, 2015 /PRNewswire/ — Relmada Therapeutics, Inc. (OTCQB: RLMD) a clinical-stage company developing novel therapies for the treatment of chronic pain, today announced topline results of a proof-of-concept pharmacokinetic study in healthy volunteers using its BuTab (REL-1028), an investigational, oral formulation of buprenorphine, an opioid that is broadly used to treat both addiction and chronic pain. BuTab is designed to be delivered orally and reach safe and effective blood levels of buprenorphine through the gastrointestinal route of administration due to its modified release profile. There are currently no commercially available oral formulations of buprenorphine that result in gastrointestinal absorption.

“We are very pleased to have demonstrated for the first time that buprenorphine can be delivered at therapeutic blood levels in an orally ingestible form,” said Sergio Traversa, CEO of Relmada Therapeutics. “These results clearly support the premise that BuTab can be a successful, first-in-class, orally ingestible buprenorphine product that we expect would be enthusiastically accepted in the multi-billion dollar market for buprenorphine products.”

Dr. Traversa continued, “The speed with which we completed this initial study, while also continuing to advance the other products in our pipeline, underscores the expertise of our management team, and our commitment to the exciting pain therapy field and stockholder value creation. With our solid development pipeline, Relmada is in an even stronger position than when we entered 2015. Throughout my more than twenty-five years career in the healthcare sector, I have never been more excited about the opportunities we expect are achievable for Relmada, particularly given the significant value creation opportunities that we believe are possible in the next 12 to 24 months.”

The clinical study conducted by INC Research, a leading global contract research organization (CRO), was designed to assess the safety, tolerability, and pharmacokinetics of BuTab in approximately 30 healthy volunteers. The key objective of the study was to assess if buprenorphine can be delivered orally and reach safe and effective blood levels through the gastrointestinal route of administration, which was achieved based on the topline analysis. Specifically, the absolute bioavailability of BuTab relative to intravenous (IV) administration exceeded published data with non-modified buprenorphine and compares favorably with a currently marketed transdermal patch¹. There were no safety or tolerability issues. The

data generated by this study will inform the design of subsequent clinical pharmacology studies.

“I’m very encouraged by these data on BuTab,” said Danny Kao, Ph.D., J.D., senior vice president of pharmaceutical development and chief intellectual property counsel at Relmada. “The bioavailability is already in the clinically relevant range for the non-refined formulations and higher than other products I’ve worked with, such as Opana® ER (oxycodone), an opioid pain medication. Based on my 20 year experience in developing formulations of opioids, I expect that we are very well positioned to develop a very valuable product.”

Conference Call and Webcast

As previously announced, members of Relmada’s senior management team will hold a conference call today at 8:30 a.m. ET. Also participating in the conference call is one of Relmada’s scientific advisors, Gavril Pasternak, M.D., Ph.D., Anne Burnett Tandy Chair in Neurology at Memorial Sloan-Kettering Cancer Center and laboratory head in the Molecular Pharmacology and Chemistry Program within the Sloan-Kettering Institute. Dr. Pasternak’s research focuses on opioid receptors and their mechanisms of action. He has demonstrated the importance of different sets of mu receptor subtypes in the actions of various opioid analgesics and identified a set of subtypes that offer a unique target for the development of analgesics lacking opioid side-effects.

The dial-in numbers are (877) 869-3847 for domestic callers and 201-689-8261 for international callers. A live webcast of the conference call and replay will be available online from the investor relations page of the Company’s corporate website at www.relmada.com.

About Relmada Therapeutics, Inc.

Relmada Therapeutics is a clinical-stage, publicly traded specialty pharmaceutical company developing novel versions of proven drug products together with new chemical entities that potentially address areas of high unmet medical need in the treatment of pain. The Company has a diversified portfolio of four lead products at various stages of development including d-Methadone (REL-1017) its N-methyl-D-aspartate (NMDA) receptor antagonist for neuropathic pain; topical mepivacaine (REL-1021), its orphan drug designated topical formulation of the local anesthetic mepivacaine; oral buprenorphine (REL-1028) its oral dosage form of the opioid analgesic buprenorphine; and LevoCap ER (REL-1015), its abuse resistant, sustained release dosage form of the opioid analgesic levorphanol. The Company’s product development efforts are guided by the internationally recognized scientific expertise of its research team. The Company’s approach is expected to reduce clinical development risks and costs while potentially delivering valuable products in areas of high unmet medical needs. For more information, please visit Relmada’s website at: www.relmada.com.

Important Stockholder Information

The Company will hold its 2015 Annual Meeting of Stockholders on December 30, 2015. On November 27, 2015, the Company filed with the U.S. Securities and Exchange Commission (the “SEC”) and mailed to its stockholders a definitive proxy statement in connection with the Annual Meeting and the solicitation of proxies (the “2015 Proxy Statement”). The 2015 Proxy Statement contains important information about Relmada, the Annual Meeting and related matters.

INVESTORS AND SECURITY HOLDERS ARE URGED TO READ THE 2015 PROXY STATEMENT AND ANY OTHER RELEVANT SOLICITATION MATERIALS WHEN THEY BECOME AVAILABLE BECAUSE THESE DOCUMENTS CONTAIN IMPORTANT INFORMATION.

The 2015 Proxy Statement and other relevant solicitation materials (when they become available), and any and all documents filed by the Company with the SEC, may be obtained by investors and security holders free of charge at the SEC's web site at www.sec.gov. In addition, Relmada's filings with the SEC, including the 2015 Proxy Statement and other relevant solicitation materials (when they become available), may be obtained, without charge, from Relmada by directing a request to the Company at 757 3rd Avenue, Suite 2018, New York, New York 10017, Attention: Senior Vice President Finance and Corporate Development. Such materials are also available at ir.relmada.com/all-sec-filings.

Relmada and its directors, officers and employees are deemed to be participants in the solicitation of proxies from Relmada's stockholders in connection with the Annual Meeting. Information regarding Relmada's directors and executive officers, including a description of their direct and indirect interests by security holdings, is contained in the 2015 Proxy Statement and in Relmada's 2015 Annual Report on Form 10-K filed with the SEC on September 11, 2015 (the "2015 Annual Report").

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. We may from time to time make written or oral statements in this letter, the proxy statements filed with the SEC communications to stockholders and press releases 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. These forward-looking statements are based upon management's current expectations, estimates, assumptions and beliefs concerning future events and conditions and may discuss, among other things, anticipated future performance, expected product development, product potential, future business plans and costs. 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. 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 of the risks, uncertainties and other factors that may affect future results and that the risks described herein should not be considered to be a complete list.

¹ BUTRANS product prescribing information

OPANA® is a U.S. registered trademark of Endo Pharmaceuticals Inc.

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To view the original version on PR Newswire, visit: <http://www.prnewswire.com/news-releases/relmada-therapeutics-announces-additional-information-regarding-positive-topline-results-for-proof-of-concept-study-with-butab-300191069.html>

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