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Relmada Therapeutics Acquires Potential Therapy for Tourette Syndrome from Asarina Pharma AB

Relmada purchases Sepranolone, a Phase 2b ready asset, for the treatment of Tourette syndrome (TS) and other compulsion-related conditions from Asarina Pharma AB

Phase 2a results signaled improvement in Tourette symptoms, quality of life and robust overall safety, supporting Sepranolone as a new potential first line treatment option for TS

Sepranolone (isoallopregnanolone) is a first-in-class compound from new subgroup of neurosteroids known as GAMSAs- $GABA_A$ Modulating Steroid Antagonists - acting selectively on the $GABA_A$ pathway, potentially alleviating the negative effect of Allopregnanolone in Tourette syndrome and other compulsive disorders

CORAL GABLES, Fla., Feb. 06, 2025 (GLOBE NEWSWIRE) -- Relmada Therapeutics, Inc. (Nasdaq: RLMD, “Relmada”, “the Company”), a clinical-stage biotechnology company, today announced the acquisition of Sepranolone, a Phase 2b ready neurosteroid, from Asarina Pharma AB (Asarina), being developed for the potential treatment of Tourette syndrome (TS) and other compulsive disorders.

“We are very pleased to announce this agreement with Asarina. Sepranolone aligns with our Company’s mission to find solutions for difficult-to-treat central nervous system (CNS) disorders. There is a serious unmet need for improved TS therapies not only reducing tics but also improving quality of life without serious side effects. We have been impressed by the encouraging Phase 2a efficacy signal with clinically meaningful tic reductions and quality-of-life improvements, combined with a robust safety data package showing no CNS off-target effects, that we believe reflect the compound’s selective binding properties,” said Sergio Traversa, Chief Executive Officer of Relmada. “We believe that this transaction is an excellent fit with our objective to build shareholder value by leveraging our core competencies of identifying and developing innovative compounds.”

Luca Pani, MD, Professor of Clinical Psychiatry at the University of Miami Miller School of Medicine, commented, "While current treatments for Tourette syndrome provide only modest tic reduction and are often accompanied by significant side effects, the Phase 2a data suggest that Sepranolone has the potential to offer meaningful symptom relief with a more favorable safety profile. These findings are promising, and I look forward to seeing further clinical development of this novel therapy.”

“Late last year we announced that Relmada would explore strategic assets and strategic options,” commented Maged Shenouda, Chief Financial Officer of Relmada. “Based on our extensive due diligence, including a carefully conducted review of the clinical and regulatory data, and consultation with well-respected outside experts, we believe the promising Phase 2a data suggest that Sepranolone has the potential to become first line treatment for TS.”

Clinical Data on Sepranolone

Sepranolone (isoallopregnanolone) is a first-in-class GABAA Modulating Steroid Antagonist (GAMSA), which selectively targets the GABAA ($GABA_A$) pathway to counteract the effects of Allopregnanolone, a neurosteroid implicated in TS and other compulsive disorders.

Data from an open-label Phase 2a randomized study demonstrated that Sepranolone has the potential to improve TS symptoms versus standard of care alone, as measured by changes in the YGTSS scoring system (the world-standard Yale Global Tic Severity Scale) compared to baseline. In the 12-week, dual-center, parallel-group study, 26 subjects were treated with Sepranolone (10 mg, administered by subcutaneous injection twice weekly in addition to standard of care (SOC) versus standard of care alone.

The Phase 2a results showed competitive tic reduction and improved quality of life while displaying no CNS off-target effects. Sepranolone not only reduced tic severity in its primary clinical endpoint as measured by YGTSS by 28% (p=0.051) – but also achieved positive results in four key secondary endpoints compared with standard of care:

69% greater increase of Quality of Life (using the Gilles de la Tourette Syndrome Quality of Life total score (GTS-QOL)

50% greater reduction in impairment (YGTSS)

44% greater reduction of the premonitory urge to tic (PUTS – the Premonitory Urge to Tic scale)

no off-target CNS effects or systemic side effects – a crucial metric for CNS drugs in an indication where legacy and new treatments in developments involve sometimes severe side effects

Strategic Outlook

Relmada continues to evaluate additional product and strategic opportunities. The Company anticipates hosting an investor update on Sepranolone's next development steps later in 2025.

About the Asarina Agreement

Under the terms of the agreement, Relmada acquired full global ownership rights to Sepranolone from Asarina Pharma AB, a Swedish biopharmaceutical company through an asset purchase agreement for EUR 3 Million.

About Neurotransmitter Modulators and Sepranolone

Sepranolone is a pioneering GAMSA that selectively inhibits the effects of Allopregnanolone, a neurosteroid linked to compulsive disorders such as TS and obsessive-compulsive disorder (OCD). Evaluated in multiple clinical neuro/hormonal studies involving over 335 participants, Sepranolone has demonstrated a favorable safety profile.

GABA (γ-aminobutyric acid) is the brain's primary inhibitory neurotransmitter, helping to regulate anxiety and compulsive disorders. While Allopregnanolone typically enhances

GABA's calming effects, in some individuals it paradoxically exacerbates anxiety and compulsive. Sepranolone normalizes GABAA receptor activity by targeting two specific receptor subtypes (alpha-2 and alpha-4) without directly interfering with GABA signaling, making it a novel and selective treatment approach for TS and related disorders.

Sepranolone is protected by multiple issued patents until 2038.

About Tourette syndrome (TS)

Tourette syndrome is a complex neurological condition characterized by involuntary tics. The Centers for Disease Control and Prevention (CDC) estimates that more than 350,000 children in the U.S. have TS, with onset typically occurring between ages five and ten. Though symptoms often improve in adulthood, many individuals experience chronic tics and associated psychosocial challenges. Existing treatments include dopamine D2 blockers, atypical antipsychotics, botulinum toxin injections, cognitive behavioral therapy (CBIT), and deep brain stimulation, but these options are often limited by significant side effects.

TS is believed to be influenced by genetic, environmental, and neurochemical factors, including the role of Allopregnanolone in triggering compulsive behaviors. Current treatments target dopamine and other neurotransmitters, but the Company believes Sepranolone's modulation of Allopregnanolone offers a novel and potentially safer alternative.

About Relmada Therapeutics, Inc.

Relmada Therapeutics is a clinical-stage biotechnology company focused on developing innovative therapies for central nervous system (CNS) and metabolic disorders. With a commitment to advancing breakthrough treatments, Relmada strives to improve patient outcomes and quality of life. For more information, visit 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. 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 potential failure of clinical trial results to demonstrate statistically and/or clinically significant evidence of efficacy and/or safety, failure of top-line results to accurately reflect the complete results of the trial, failure of planned or ongoing preclinical and clinical studies to recapitulate the results of prior studies, potential failure to secure FDA agreement on the regulatory path for Sepranolone or that future Sepranolone clinical results will be acceptable to the FDA, failure to secure adequate Sepranolone drug supply and the other 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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