



Regenacy Pharmaceuticals Announces Completion of Enrollment for Phase 2 Study in Diabetic Peripheral Neuropathy & \$9.3 Million Series B Financing

-Company's lead compound, ricolinostat, is well-positioned to advance as a potential first-in-class treatment for diabetic and other peripheral neuropathies-

WALTHAM, Mass., August 24, 2022 – [Regenacy Pharmaceuticals Inc.](#), a clinical-stage biopharmaceutical company developing breakthrough treatments for diabetic and other peripheral neuropathies, announced completion of enrollment of the company's phase 2 study of ricolinostat, an oral selective histone deacetylase 6 (HDAC6) inhibitor, in painful diabetic peripheral neuropathy (DPN). The company also announced the closing of a \$9.3 million Series B financing led by Cobro Ventures with participation from Taiwan Capital Management Corporation, 3E Bioventures Capital, Yonjin Venture, and other undisclosed private investors.

Painful DPN is characterized by debilitating symptoms that include pain, aberrant sensation, and loss of motor and sensory function. There is an important medical need for new treatments since available therapies do not address the full spectrum of signs and symptoms and offer only limited relief for many patients. Ricolinostat, and other HDAC6 inhibitors, have shown efficacy in animal models of DPN, chemotherapy-induced peripheral neuropathy (CIPN) and Type 2 Charcot Marie Tooth (CMT) disease, and have demonstrated a promising safety and tolerability profile. The ongoing double-blinded placebo-controlled clinical study, which recently completed enrollment, assesses the efficacy of ricolinostat in patients with painful DPN and other neuropathic symptoms. Initial results are expected to be available later this year. Regenacy plans to use the additional financing from this Series B to continue advancing the ricolinostat clinical development program.

"Regenacy is committed to exploring ricolinostat's unique and differentiating potential to address the underlying pathophysiology of small fiber neuropathies," said David Michelson, M.D., Regenacy's Chief Medical Officer. "The compelling data we have seen in preclinical studies indicate ricolinostat's selective inhibition of HDAC6 may provide meaningful relief to patients suffering from painful DPN and other neuropathies, and we look forward to its continued progression in the clinic."

"We are energized by the ongoing support of our investors who share in our mission to address the underlying causes of peripheral neuropathy," said John Rocha, Regenacy's Chief Financial Officer. "This Series B positions Regenacy for continued progress as we uncover the potential of ricolinostat to restore peripheral nerve function."

“We at Regency believe that ricolinostat shows first-in-class potential to go beyond symptomatic treatment and instill lasting disease-modifying effects for patients with peripheral neuropathies,” said Simon Jones, Ph.D., Regency’s President and Chief Executive Officer. “This Series B financing comes at a pivotal stage in our clinical development, as we continue to evaluate ricolinostat in painful diabetic peripheral neuropathy while simultaneously advancing our joint venture Beijing 3E-Regency Pharmaceuticals Co., Ltd. to investigate ricolinostat in patients with chemotherapy-induced peripheral neuropathy (CIPN) in China.”

Concurrent with the financing, Todd Kaloudis, Managing Director at Cobro Ventures, has joined Regency’s Board of Directors. Additionally, Regency announced the appointment of William W. Chin, M.D., SVP of Clinical and Translational Science at Frequency Therapeutics, as Executive Chairman of the Board and Michael Huang, Managing Partner at Taiwan Capital, as Vice-Chairman, effective immediately. Mr. Huang has served on Regency’s Board since 2020, and Dr. Chin has served since 2018 and is Chairman of Regency’s Scientific Advisory Board.

About Ricolinostat

Ricolinostat, an oral, selective histone deacetylase 6 (HDAC6) inhibitor, has the potential to become the first-in-class treatment that reverses the underlying peripheral neuropathy, thereby relieving pain, numbness, motor function loss, and all other symptoms of the disease. Ricolinostat restores nerve function by inhibiting HDAC6, which reestablishes the transport function of microtubules in the axon of the nerve cell. A functioning microtubule transport system is the key to restoring nerve function because nerves rely on this network to supply the energy and nutrients necessary to maintain the nerve signaling in the ends of the nerves in the skin and muscles of the feet and hands. When this transport is disrupted by a disease like diabetes or neurotoxic drugs used in chemotherapy, nerve cells can malfunction and send random signals (pain, tingling, muscle spasms) or no signal at all (numbness, paralysis). Multiple preclinical animal models have demonstrated that HDAC6 inhibition restores nerve fibers, leading to the reversal of both pain and numbness in peripheral and other neuropathies, such as diabetic peripheral neuropathy (DPN), chemotherapy-induced peripheral neuropathy (CIPN) and Charcot-Marie-Tooth disease Type 2, an orphan-designated disease.

About Regency

Regency Pharmaceuticals, Inc. is a clinical-stage biopharmaceutical company regenerating biological function by protein acetylation for the treatment of diabetic and other peripheral neuropathies and other chronic conditions. The company’s selective inhibition technology provides superior safety profiles and potential enhanced efficacy compared to non-selective HDAC inhibitors. Regency selectively inhibits histone deacetylase 6 (HDAC6) to restore normal intracellular protein and organelle transport in peripheral neuropathies, and also has a portfolio of selective HDACs 1 and 2 inhibitors that have potential to treat major blood diseases such as leukemia, sickle cell disease, β -thalassemia, and cognitive dysfunction in neurological disorders.

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