

# Regenacy Announces the Formation of a Joint Venture with 3E Bioventures to Develop Ricolinostat in China and the Start of a U.S. Phase 2 Study in Painful Diabetic Peripheral Neuropathy

WALTHAM, Mass., December 21, 2020 – Regenacy Pharmaceuticals, a clinical-stage biopharmaceutical company developing breakthrough treatments for diabetic and other peripheral neuropathies, and 3E Bioventures Capital, a healthcare focused fund dedicated to investing in innovative therapeutics and frontier biomedical technologies, today announced the formation of the joint venture company Beijing 3E-Regenacy Pharmaceuticals Co., Ltd. (BC Regenacy). BC Regenacy will have an exclusive license to Regenacy's lead compound ricolinostat, an oral, selective histone deacetylase 6 (HDAC6) inhibitor, for development in peripheral neuropathies in mainland China, Hong Kong and Macau. BC Regenacy's lead program will evaluate the safety and efficacy of ricolinostat in patients with chemotherapy-induced peripheral neuropathy (CIPN) in China.

Regenacy also announced today that it has initiated patient enrollment into a Phase 2 study of ricolinostat for the treatment of painful diabetic peripheral neuropathy (DPN). The study, which includes a 3-month, placebo-controlled, double-blind, randomized period assessing the efficacy and safety of ricolinostat, is being conducted at multiple investigative centers in the United States and will enroll approximately 274 patients with painful DPN. Results are expected to be available in 2022.

Additionally, Regenacy announced the issuance of U.S. Patent 10,858,323, which covers the use of HDAC6 inhibitors for the treatment of DPN.

"The creation of this joint venture and the initiation of our phase 2 study in painful DPN mark significant milestones for Regenacy. The clinical study in diabetes together with the joint venture's initial focus on CIPN enables the evaluation of ricolinostat in two peripheral neuropathy indications simultaneously," said Simon S. Jones, Ph.D., Regenacy's President and Chief Executive Officer.

"Preclinical studies demonstrate that ricolinostat has the potential to restore nerve function in multiple peripheral neuropathies, so we are pleased that BC Regenacy will be able to concurrently study ricolinostat in the clinic for CIPN while Regenacy remains focused on painful DPN," said David Michelson, M.D., Regenacy's Chief Medical Officer.

"Chemotherapy-induced peripheral neuropathy continues to be a debilitating complication for many cancer patients undergoing chemotherapy, and the robust science supporting ricolinostat has been validated by compelling results in preclinical studies," said Frank Yan, Ph.D., Partner at 3E Bioventures Capital. "As there are no approved therapies to combat CIPN, we are excited to start evaluating ricolinostat in this indication through our partnership with the Regenacy team."

"Current peripheral neuropathy treatments aim to only address the symptoms of the disease and are often poorly tolerated and minimally effective," said Marc Cohen, Regenacy's Executive Chairman. "By addressing the abnormalities that lead peripheral nerves to misfire, ricolinostat may not only provide symptomatic relief for peripheral neuropathies, but also address the underlying disease process."

Locust Walk served as Regenacy Pharmaceuticals' transaction advisor.

# **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 Regenacy**

Regenacy 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. Regenacy 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,  $\beta$ -thalassemia, and cognitive dysfunction in neurological disorders. www.regenacy.com

# **About 3E Bioventures Capital**

3E Bioventures Capital is a healthcare venture capital firm, dedicated to investing in cutting-edge life sciences and biomedical technologies, with a focus on breakthrough first-in-class therapies and disruptive cross-disciplinary innovations in medical devices and diagnostics. 3E Bioventures takes on a science-driven, entrepreneur-friendly investment philosophy by working closely with companies and research institutions to develop drugs or products that have strong unmet medical needs. With offices in Beijing, Shanghai, and the San Francisco Bay Area, 3E Bioventures leverages its experience, capabilities, and network to help companies tap into markets and resources across the Pacific and advance with greater speed and capital efficiency. The motto of 3E Bioventures Capital is captured in its name 3E: Expertise, Efficiency, Execution.

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