

Bayhill Therapeutics Enters Exclusive, Worldwide Collaboration with Genentech for BHT-3021 in Type 1 Diabetes

Clinical Data Presented at ADA Indicates Potential to Preserve Beta Cell Function and Improve Glycemic Control

SAN MATEO, Calif.--(BUSINESS WIRE)-- Bayhill Therapeutics Inc. announced today that it has entered into an exclusive worldwide license agreement for the development and potential commercialization of BHT-3021 with Genentech, Inc. a wholly-owned member of the Roche Group. BHT-3021 is Bayhill's DNA based antigen specific immunotherapy currently in a phase I/II clinical trial in patients with type 1 diabetes (T1D).

Under the terms of the agreement, Genentech will make an upfront payment of \$25M in cash and equity, with additional development, regulatory and sales milestone payments potentially exceeding \$325M. Bayhill will also receive competitive escalating royalties on annual net sales. Bayhill will be responsible for completing the on-going phase I/II trial, while Genentech will be responsible for all future research, development, manufacturing and commercialization efforts. Genentech will reimburse Bayhill the remaining costs of the phase I/II trial and will fund all future expenses.

Under the terms of the agreement, Bayhill retains rights to opt-in on future development as well as an option to co-promote in North America.

Mark W. Schwartz, PhD, CEO and President of Bayhill Therapeutics, commented, "BHT-3021 represents a truly novel approach to treating type 1 diabetes. We believe this collaboration with Genentech reflects the significant potential of our approach to antigen specific tolerance, and will allow us to accelerate and expand the development of BHT-3021, while continuing to develop additional products from our BHT-DNA platform."

"The ultimate goal for treatment of autoimmune disease is antigen specific therapy," commented Lawrence Steinman M.D., Founder, Director and Chairman of Bayhill's Scientific Advisory Board. "Genentech has long been an innovator in immunology based therapies, making it a strong collaborator for BHT-3021. We look forward to working with the Genentech team on the development of BHT-3021."

BHT-3021 Presentation at American Diabetes Association (ADA)

BHT-3021 was the subject of a recent presentation by Dr. Peter Gottlieb of the Barbara Davis Center at the American Diabetes Association's 69th Scientific Sessions in New Orleans. The abstract, entitled "Interim Results of a Phase I/II Clinical Trial of a DNA Plasmid Vaccine (BHT-3021) for Type 1 Diabetes," presented interim results from a randomized, blinded, placebo-controlled, dose escalation trial in T1D patients. Patients were randomized 2:1 to receive a weekly intra-muscular injection of BHT-3021 (0.3 mg, 1 mg, 3 mg or 6 mg) or placebo for 12 weeks. Data presented included pancreatic function as measured by C-peptide and safety data from a total of 42 C-peptide positive patients. Data from the 1 mg dose cohort was available out to 12 months, and data from the 0.3 mg, 3 mg, and 6 mg dose groups

were available out to six months. Patients in all 4 dose cohorts exhibited a preservation of C-peptide compared to placebo. Adverse event (AE) and clinical laboratory data indicate that BHT-3021 is safe and well-tolerated. No treatment related serious adverse events have been reported. Most AEs were mild or moderate in severity.

About BHT-3021

BHT-3021 is a plasmid encoding proinsulin, designed to target specific pathogenic immune cells responsible for the autoimmune response in type 1 diabetic patients. The compound has shown efficacy in NOD mice, a model of type 1 diabetes. In the current phase I/II trial, patients receiving BHT-3021 demonstrated preservation of C-peptide and an acceptable safety profile. BHT-3021 is designed to induce antigen specific tolerance by selectively turning off the errant autoimmune response attacking the pancreas. This highly specific immunomodulation action could result in the preservation of pancreatic function and improved long term health in type 1 diabetic patients.

About Bayhill Therapeutics

Bayhill Therapeutics is a clinical-stage biopharmaceutical company at the forefront of developing novel and targeted treatment candidates for autoimmune diseases. Leveraging its proprietary therapeutic BHT-DNA™ platform, the Company's product candidates are designed to restore patient's immunological "tolerance" to self antigens to a normal state by selectively eliminating specific, harmful immune responses while leaving the rest of the immune system intact. Through a targeted and selective approach, Bayhill's product candidates have the potential to deliver superior efficacy, safety and tolerability relative to current therapies. For more information please visit www.bayhilltherapeutics.com/

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