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Preclinical Advancement of Novel Mechanism-of-Action Therapeutics to Combat Type 2 Diabetes in US Veterans

Principal Investigator: NEELAKANTAN, HARSHINI
Institution Receiving Award: RIDGELINE THERAPEUTICS, LLC
Program: PRMRP
Proposal Number: PR180216
Award Number: W81XWH-19-1-0290
Funding Mechanism: Expansion Award - Funding Level 3
Partnering Awards:
Award Amount: $4,192,268.00

View Technical Abstract

PUBLIC ABSTRACT

Project Overview: This Peer Reviewed Medical Research Program Expansion Award will enable Ridgeline Therapeutics to rapidly move a recently developed drug candidate for obesity-linked type 2 diabetes (T2D) and prediabetes to first-in-human clinical trials. Importantly, this drug candidate emerged from a high-risk high-reward Fiscal Year 2014 (FY14) Discovery Award (DA) project (PR141776; Principal Investigator: Dr. Watowich) that discovered novel small molecules that control body fat in obese individuals. In the past year, the Watowich laboratory has extended this highly successful DA project to ultimately find a promising drug candidate (termed RLT-72484) that appears to reduce obesity and obesity-linked T2D/prediabetes. Moving this drug candidate from a research laboratory to clinical practice is a challenging undertaking, and best performed by a biotechnology company. Thus, RLT-72848 has been licensed to Ridgeline Therapeutics (Founder/CEO: Dr. Watowich), an early-stage biotechnology company intent on making small molecule therapeutics available for patient use. Ridgeline Therapeutics will use Expansion Award funds and its strategic partnerships with established world-leading drug development companies to advance RLT-72484 through regulated preclinical safety and manufacturing studies. This project will culminate in an Investigational New Drug (IND) application to the US Food and Drug Administration (FDA) to obtain approval to begin clinical trials. Completing IND filing will greatly increase the likelihood that RTL-72484 becomes approved drug to combat obesity-linked T2D/prediabetes among US Veterans, military Service members, and beneficiaries (as well as the general US population).

Relevance to Topic Area: Our project clearly satisfies the Fiscal Year 2018 Peer Reviewed Medical Research Program Topic Area of Diabetes and directly addresses the major area of encouragement “identification and/or evaluation of interventions to reduce the development of diabetes among individuals meeting the clinical criteria for prediabetes/T2D.”

Project Outcomes and Impact: Our Expansion Award project will rapidly complete a series of highly regulated safety and manufacturing studies for our small molecule drug candidate (RLT-72484); these studies are compliant with current FDA drug guidelines. These studies represent a preponderance of the FDA-mandated testing that must be included as part of an application (termed an Investigational New Drug [IND] application) to the FDA for approval to test a new drug in humans. In Quarter 4, 2021, at the conclusion of our Expansion Award, the results from this project will be compiled into an IND application and submitted to the FDA. Clinical trials of our novel drug to treat obesity-linked T2D/prediabetes will begin soon thereafter.

Medical Relevance and Patient Benefits: Approximately 22% of Veterans receiving care from the Department of Veterans Affairs (VA) have T2D and are either obese or overweight, a rate that is two-fold higher than the general US adult population. An additional 20% of Veterans are prediabetic and obese. The Department of Defense recognizes that pervasive diabetes among Veterans is major health crisis and has made reducing T2D among overweight/obese Veterans a top focus area. Clinical evidence has shown that even modest (e.g., 5%-7%) weight loss can improve blood sugar control and delay the progression of T2D/prediabetes in obese individuals. Unfortunately, VA-sponsored lifestyle modification (i.e., weight loss and exercise) programs have produced little sustained weight loss and no long-term improvements in blood sugar levels among the participants. Thus, there is an unmet need for new interventions to treat obesity-linked T2D in Veterans. Since our innovative drug candidate reduces body weight >8%, shrinks visceral fat >30%, and improves fasting hyperglycemia and oral glucose tolerance, it is expected to provide a novel differentiated treatment to prevent or delay the onset of T2D among obese/overweight US Veterans.

Objectives and Project Design: The overarching goal of our Expansion Award project is to complete most of the regulated preclinical studies that are needed to support filing an IND application with the FDA for approval to test our drug candidate in humans. With our global chemistry partner, we will complete FDA-approved, large-scale manufacture of our lead under exacting specifications. With our drug development partner, the manufactured drug candidate will be rigorously tested in several animal species to ensure that

it causes no adverse effects and is safe to use in human clinical trials. To ensure the success of this project, Ridgeline has a highly assembled an accomplished scientific and management team, a Business Advisory Board (BAB) with extensive pharmaceutical industry experience, and expert consultants with wide-ranging experience at developing small molecule drugs.

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