Carmot Therapeutics Announces Investigational New Drug (IND) Clearance for CT-868, a Dual GLP-1 and GIP Receptor Modulator for the Treatment of Overweight and Obese Patients with Type 2 Diabetes

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Carmot Therapeutics, Inc. (Berkeley, CA), a clinical-stage biotechnology company applying its proprietary Chemotype Evolution (CE) technology to discover and develop disease-modifying therapies in metabolic disease and cancer, announced today U.S. Food and Drug Administration (FDA) clearance of an IND application for CT-868, Carmot's dual GLP-1 and GIP receptor modulator.

The IND will enable Carmot to initiate a Phase 2 randomized, double-blind, placebo-controlled, multi-center trial to evaluate the efficacy, safety, and tolerability of CT-868 over 26 weeks in overweight and obese patients with type 2 diabetes. Additional studies to investigate the mechanism of action of CT-868 in non-diabetic insulin resistant individuals and in diabetics are also planned under this IND. Both studies are planned to initiate in the second half of 2021.

"Treatment of type 2 diabetes and associated metabolic diseases is currently undergoing a transformative change with the advent of dual activators of the GLP-1 and GIP incretin pathways. Through deep insights into incretin function, Carmot has developed dual modulators with improved therapeutic index. CT-868, the first drug-candidate to emerge from these efforts, has the potential to provide best-in-class weight loss for patients with type 2 diabetes and help reverse the course of the disease," said Manu Chakravarthy, MD, PhD, Chief Medical Officer and Head of R&D at Carmot. "In the Phase 1 trial, CT-868 demonstrated compelling pharmacodynamic activity across several clinical measures in overweight and obese healthy individuals, along with a safe and generally well-tolerated profile. We are now expanding these observations in overweight and obese patients with type 2 diabetes to demonstrate CT-868's effects on glycemic control, weight loss and tolerability."

About CT-868

CT-868 is a dual GLP-1 and GIP receptor modulator with a unique pharmacological profile optimized for improved tolerability at the GLP-1 receptor. The combined action of GLP-1 and GIP result in greater body weight loss and glucose control. CT-868 is dosed once daily to maximize efficacy and tolerability.

About Obesity and Type 2 Diabetes.

Obesity accounts for 80-85% of the risk of developing type 2 diabetes, and obese individuals are up to 80 times more likely to develop type 2 diabetes than those with a BMI of less than 22 kg/m^2. More than 2 out of every 5 adults (42%) are obese and nearly 3 out of every 4 adults (74%) are overweight in the United States with adulthood obesity accounting for nearly $173 billion in annual medical expenses. By 2030, nearly 1 in every 2 adults in the US will be obese. Annually, this increase is anticipated to result in more than a million extra cases of type 2 diabetes, heart disease and cancer. Another major driver for the pathogenesis of type 2 diabetes is insulin resistance, the body's inability to respond appropriately to insulin and carry out its actions. Carmot is developing a portfolio of therapeutics that target these root causes (obesity and insulin resistance) to provide durable benefit and improve quality-of-life for patients.

About Carmot Therapeutics, Inc.

Carmot Therapeutics ("Carmot") is focused on the discovery and development of transformative therapies for patients with serious unmet medical needs in metabolic diseases and cancer. Carmot applies Chemotype Evolution (CE), a pioneering drug discovery technology, in combination with unique biological expertise to identify innovative and superior therapeutics. In metabolic disease, Carmot is combining CE with novel insights into incretin receptor signaling to develop a broad, valuable pipeline of peptide-based and small molecule therapeutics. Carmot's dual GLP-1/GIP receptor modulator has entered Phase 2 development and has the potential to be best in a new class of treatments for type 2 diabetes and related indications. In addition, Carmot is using CE to identify novel covalent inhibitors and to develop new therapeutics targeting major oncogenic pathways, internally and with partners. Carmot has successfully applied CE with strategic partners including the discovery collaboration with Amgen that led to LUMAKRAS™ (sotorasib), the first KRAS inhibitor to enter the clinic and advance to FDA New Drug Application review.

Contact Information:

James Watson, Chief Business Officer
bd@carmot.us
www.carmot.us

Investors:
Stern Investor Relations, Inc.
Stephanie Ascher
stephanie.ascher@sternir.com
www.sternir.com