Carmot Therapeutics Commenced Phase 2 Clinical Trial of Novel Dual GLP-1/GIP Receptor Agonist CT-868 for the Treatment of Type 1 Diabetes

– Randomized, placebo-controlled trial to assess 16-week treatment with CT-868 in participants with overweight or obesity with type 1 diabetes (T1D) –

– A second mechanistic clinical trial is ongoing to assess effects of CT-868 treatment vs. liraglutide on glucose homeostasis in T1D –

BERKELEY, Calif., November 15, 2023 (GLOBE NEWSWIRE) — Carmot Therapeutics Inc. (Carmot), a clinical-stage biotechnology company dedicated to developing life-changing therapeutics for people living with metabolic diseases including obesity and diabetes, today announced that it has commenced a Phase 2 clinical trial of its once-daily dual GLP-1/GIP receptor agonist, CT-868, in adult participants with overweight or obesity with T1D.

Carmot has previously presented results from another Phase 2 clinical trial of CT-868 that demonstrated a placebo-adjusted reduction in HbA1c in the 4.0 mg dose of 2.31% from baseline at Week 26 in overweight or obese participants with type 2 diabetes (T2D) and was well-tolerated, with the most common adverse effects being GI-related and mostly mild in severity. These data along with our previous preclinical and clinical mechanism of action studies continue to provide both clinical and mechanistic rationale to pursue CT-868 as an adjunct to insulin for the treatment of T1D. In addition to the Phase 2 clinical trial announced today, Carmot has an ongoing Phase 1b active comparator crossover clinical trial to assess the effects of CT-868 treatment on glucose homeostasis compared to liraglutide in participants with T1D. CT-868 is one of three clinical-stage product candidates in Carmot's pipeline of therapeutics for the potential treatment of obesity and diabetes.

"This Phase 2 clinical trial represents an important next step in the CT-868 clinical program—with it, we look forward to evaluating the potential for CT-868 as an adjunctive treatment for people living with T1D," said Manu Chakravarthy, MD, PhD, Carmot's Chief Scientific & Medical Officer. "We remain very pleased with the progress across all three of our clinical programs and expect to have multiple data readouts from our obesity and diabetes pipeline throughout 2024."

The Phase 2 clinical trial in adult participants with overweight or obesity with T1D is designed to compare the effect of CT-868 versus placebo on the percent change in HbA1c from baseline to Week 16 of treatment, along with several other continuous glucose monitoring (CGM)-related metrics and other relevant endpoints. Carmot anticipates enrolling approximately 95 participants at clinical trial centers across the United States. All participants will continue to receive insulin therapy using either an insulin pump or multiple daily insulin injections, and all participants will wear a CGM device throughout the clinical trial. Alongside their designated treatment, participants will receive guidance on managing their diabetes, including monitoring blood glucose levels, diet and exercise recommendations. Additional information can be found on clinicaltrials.gov using the trial identifier NCT06062069.

The Phase 1b mechanism of action crossover clinical trial in 24 T1D participants will assess the effect of CT-868, liraglutide or placebo on glucose homeostasis as assessed by a mixed meal tolerance test in a weight-independent manner. Additional information can be found on clinicaltrials.gov using the trial identifier NCT05794581.

About CT-868
CT-868 is a once-daily subcutaneous injectable, dual GLP-1/GIP receptor agonist being developed as an adjunct to insulin for the treatment of people with type 1 diabetes (T1D) with overweight or obesity. CT-868 was designed to be potent on both GLP-1 and GIP receptors with no ß-arrestin recruitment to either receptor (i.e., fully biased). It is currently being studied in a Phase 2 proof-of-concept clinical trial in people with overweight or obesity with T1D and an active comparator Phase 1b mechanism of action crossover clinical trial to assess glucose homeostasis in people with T1D.

About Carmot Therapeutics
Carmot Therapeutics is a clinical-stage biotechnology company dedicated to developing life-changing therapeutics for people living with metabolic diseases, including obesity and diabetes. Carmot's expertise in metabolic biology has enabled the development of a broad pipeline of therapeutics, including three clinical candidates: CT-388 (once-weekly subcutaneous injectable, dual GLP-1/GIP receptor agonist), CT-868 (once-daily subcutaneous injectable, dual GLP-1/GIP receptor agonist) and CT-996 (once-daily oral, small molecule GLP-1 receptor agonist), and others in preclinical development. All of these are proprietary novel compounds, wholly owned by Carmot, that have the potential to deliver an enhanced treatment response in people with metabolic diseases. For more information, visit the Carmot Therapeutics website and follow us on LinkedIn.

Forward Looking Statements
This press release contains forward-looking statements. While Carmot Therapeutics Inc. considers the projections to be based on reasonable assumptions, these forward-looking statements may be called into question by numerous risks and uncertainties, and actual results may differ materially from those anticipated in such forward-looking statements.

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