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Cytoki Pharma Presents Preclinical Data Demonstrating Weight Reduction and Improved Glucose Control with Lipidated IL-22 at ObesityWeek 2023

Lipidated IL-22 induced dose-dependent reductions in body weight and blood glucose and improvement of key metabolic parameters in murine models

CK-0045, the company's lead lipidated IL-22 candidate, is currently in Phase 1 clinical evaluation in healthy volunteers with and without obesity, with data anticipated in H1 2024

COPENHAGEN, DENMARK – October 16, 2023 – Cytoki Pharma, ApS (Cytoki), a clinical-stage biotechnology company pioneering a new class of medicines that harness IL-22 biology to drive improved outcomes for metabolic disease, today presented preclinical data demonstrating the potential of lipidated IL-22 to induce weight loss and positively impact a range of cardiometabolic risk factors at ObesityWeek 2023, held October 14-17 in Dallas.

IL-22 is an atypical, non-immunomodulatory cytokine, which selectively targets epithelial tissues, including those that play important roles in metabolic processes, such as the gut and liver. Cytoki's lipidated IL-22 analogues leverage this innate biology and offer first-in-class potential to address a range of metabolic diseases, including obesity and type 2 diabetes.

"Despite the emergence of GLP-1 therapies and a burgeoning obesity market, there is still significant need for alternative approaches that avoid substantial gastrointestinal side effects and drive healthy weight loss—reductions in body mass with further improved cardiometabolic outcomes that bolster quality of life," said Rasmus Jorgensen, Ph.D., Founder and CEO of Cytoki Pharma. "We are encouraged by these data supporting CK-0045's differentiated mode-of-action for treating diabetes and obesity and look forward to sharing data from our ongoing Phase 1 trial of CK-0045 in healthy adults with and without obesity next year."

The data presented show that subcutaneous (SC) dosing of diet-induced obese (DIO) mice with lipidated IL-22 for five weeks resulted in dose-dependent reductions in body weight of up to 20.2% at the highest dose—a comparable reduction in mass as observed with optimally dosed GLP-1 receptor agonist (GLP-1RA) semaglutide (25.2%). IL-22's mechanism of action is differentiated and complementary to that of GLP-1RAs and, as a result, lipidated Il-22 and semaglutide induced a synergistic effect on body weight loss when dosed together.

Administration of lipidated IL-22 was also shown to directly impact lipid metabolism and insulin sensitivity in DIO mice, with significant reductions in triglyceride levels and fasting insulin levels observed after five weeks of dosing versus weight-matched controls. Subsequent studies in diabetic db/db mice indicate that treatment with lipidated IL-22 normalized blood glucose levels and reduced HbA1c levels independent of food intake, accompanied by dose-dependent insulin sensitization.

CK-0045, Cytoki's lead lipidated IL-22 analogue, is currently being evaluated in a randomized, double-blind, placebo-controlled Phase 1 study designed to investigate its safety, tolerability, and pharmacokinetics following SC administration in healthy participants and otherwise healthy participants with obesity (NCT05712876). The study will include a maximum of 88 participants across the single and multiple ascending dose cohorts. Data from the study is anticipated in the first half of 2024.

The presentation details are as follows:
Title: Novel Long-Acting Lipidated Interleukin-22 Reduces Body Weight and Improves Glucose Control in Mice
Presenting Author: Martijn van de Bunt, M.D., D.Phil., Vice President of Research, Cytoki Pharma
Location: Kay Bailey Hutchinson Convention Center, Room D174
Date & Time: Monday, October 16, 11:00 am CT

About CK-0045
CK-0045 is a long-acting analogue of interleukin-22 (IL-22), an atypical, non-immunomodulatory cytokine that selectively targets epithelial cells. In-licensed from Novo Nordisk, CK-0045 incorporates validated technology to optimize the pharmacologic properties of the endogenous IL-22 protein to create a differentiated, first-in-class therapy with potential to address a broad range of metabolic diseases, including obesity and type 2 diabetes, and conditions characterized by epithelial injury, such as inflammatory bowel disease. It is being evaluated in an ongoing randomized, double-blind, placebo-controlled Phase 1 study designed to investigate its safety, tolerability, and pharmacokinetics in healthy individuals with and without obesity. For additional information about the trial, please visit clinicaltrials.gov (NCT05712876).

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About Cytoki Pharma

Cytoki Pharma is a clinical-stage biotechnology company pioneering a new class of medicines that harness IL-22 biology to drive improved outcomes for cardiometabolic disease. Cytoki's lead program, CK-0045, is a lipidated IL-22 analogue currently in Phase 1 clinical evaluation, with data anticipated in first half of 2024. The company was founded in 2019 and is led by a team of pharma industry veterans with deep expertise in the discovery and clinical development of novel drugs that address metabolic disease. The lead compound is selected from a full program of therapeutic IL-22 variants based on an exclusive license from Novo Nordisk A/S. Please visit www.cytokipharma.com or follow us on LinkedIn for additional details.

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