CYTOKI

Cytoki Pharma Announces Positive Phase 1 Data Showing Potential of CK-0045 to Improve Cardiometabolic Risk Factors

CK-0045 induced exposure-dependent reductions in body weight and improvement of key metabolic parameters in participants with obesity

Data support advancement of CK-0045 into Phase 2 proof-of-concept studies in individuals with type 2 diabetes and/or obesity

---

COPENHAGEN, DENMARK – July 23, 2024 – 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 announced positive data from a Phase 1 study evaluating the safety, tolerability, and pharmacokinetics of CK-0045, its lead lipidated IL-22 candidate, in healthy participants and otherwise healthy participants with obesity. The data signal the effect of CK-0045 across several key metabolic parameters including body weight, cholesterol, blood glucose levels, and insulin sensitivity.

“As the obesity treatment landscape continues to evolve, there remains a need for approaches that drive lasting disease modification through healthy weight loss and broader, deeper weight loss-independent metabolic effects,” said Rasmus Jorgensen, Ph.D., Founder and CEO of Cytoki Pharma. “We believe CK-0045 offers a differentiated opportunity to address obesity and type 2 diabetes, either as monotherapy or in combination with other clinical approaches and are encouraged by these first data supporting CK-0045’s unique mechanism of action.”

IL-22 is a non-immunomodulatory cytokine that selectively targets epithelial tissues such as the gut and liver. Previously reported preclinical data demonstrate the potential of lipidated IL-22 to reduce body weight and improve glucose homeostasis in mice through a novel mode-of-action.

Results from the Phase 1 study signal successful translation of the preclinical findings to humans, with confirmed target engagement based on liver and gut-derived biomarkers. Pharmacokinetic data confirm feasibility of once weekly subcutaneous dosing. CK-0045 induced exposure-dependent reductions in body mass that were complemented by beneficial reductions

in low-density lipoprotein cholesterol, blood insulin concentration, and insulin resistance—particularly in participants with reduced insulin sensitivity.

CK-0045 was safe and tolerated across the multiple ascending dose portion of the study, with all but one participant having completed dosing. The most commonly occurring side effects were mild skin reactions and a notable absence of substantial gastrointestinal effects was observed.

The available clinical data support advancement of CK-0045 into Phase 2 proof-of-concept studies in individuals with obesity and type 2 diabetes to further assess the clinical relevance of observed effects. Initiation of the Phase 2 is anticipated in the second half of 2024.

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 A/S, 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. CK-0045 has been evaluated in a randomized, double-blind, placebo-controlled Phase 1 study designed to investigate its safety, tolerability, and pharmacokinetics in healthy individuals with and without obesity (NCT05712876). CK-0045 is expected to enter Phase 2 studies in the second half of 2024.

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 that has been evaluated in a Phase 1 clinical study and is expected to enter Phase 2 clinical studies in the second half of 2024. The lead compound is selected from a full program of therapeutic IL-22 variants based on an exclusive license from Novo Nordisk A/S. The company is also advancing a broader portfolio of preclinical IL-22-based assets for the treatment of metabolic disease and inflammatory bowel disease. Cytoki 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. Please visit www.cytokipharma.com or follow us on LinkedIn for additional details.

###

Media Contact
Lia Dangelico
ldangelico@vergescientific.com
+1 540-303-0180