Walden Biosciences Announces Positive Topline Data from Phase 1+ Clinical Study of WAL0921 in Development for Treatment of Kidney Diseases

Proprietary Human anti-suPAR Monoclonal Antibody Demonstrated Safety and Reduction of Circulating Free suPAR, a Cause of Kidney Disease

Plans to Initiate Phase 2 Basket Study in Glomerular Kidney Diseases in 2Q24

CAMBRIDGE, Mass., April 15, 2024— Walden Biosciences, Inc. (Walden), a private, venture-backed clinical development stage company focused on disease-modifying, transformative therapies for the treatment of kidney diseases, today announced the results from the Company's Phase 1+ clinical study of WAL0921 in healthy subjects. WAL0921 is Walden's first-in-class, proprietary, humanized monoclonal antibody that binds circulating free soluble urokinase plasminogen activator receptor (suPAR) and its membrane bound form, uPAR, and inhibits their pathological activity, which causes kidney diseases.

Elevated levels of suPAR injure kidney tissues leading to podocytes dysfunction and associated proteinuria. The compromised kidney structure and function ultimately may lead to end-stage kidney disease requiring dialysis.

"These data from our Phase 1+ study are compelling and demonstrate WAL0921's ability to directly target and rapidly reduce free suPAR levels, and may provide a truly novel and disease-modifying approach for many kidney diseases" noted Andrew Blair, M.D., Chief Medical Officer of Walden.

The Phase 1+ clinical study was a single center, placebo-controlled, single ascending dose study of WAL0921 in five cohorts that evaluated its safety, pharmacokinetics, and pharmacodynamics in 40 healthy subjects. Data from the study showed that WAL0921 was safe, well-tolerated, and demonstrated proof-of-biology through a rapid, dose-dependent reduction in free suPAR levels.

"These data reinforce WAL0921's unique mechanism that targets a key underlying pathway of kidney disease and supports our plan to rapidly advance this promising product candidate into a Phase 2 Basket study of glomerular kidney diseases in the second quarter of 2024," stated Blaine H. McKee, Ph.D., Chief Executive Officer of Walden.

About Walden Biosciences

Walden Biosciences is a private, venture-backed clinical development-stage company focused on developing breakthrough, disease-modifying medicines to treat kidney diseases. Walden is applying novel, multi-disciplinary approaches that directly target the kidney to prevent damage, slow disease progression, and restore kidney function. Walden's programs address novel targets for therapeutic intervention, directly targeting two cell types critical for kidney function: podocytes and proximal tubular cells. Dysfunction of these cells are critical hallmarks of the majority of kidney diseases. Walden's clinical-stage program is a humanized monoclonal antibody that inhibits suPAR, a pro-inflammatory mediator that causes podocyte dysfunction and kidney disease. Walden's second most advanced program is a small molecule that is designed to restore the function of dynamin, an enzyme responsible for the maintenance of the cytoskeletal architecture and function of podocytes and proximal tubule cells. In addition to the suPAR and dynamin programs, Walden also has a novel anti-fibrotic biologic in preclinical research. All of Walden's programs offer the promise to deliver disease-modifying, breakthrough therapies that are readily combinable with the standard of care to transform the treatment of kidney disease. For more information, please visit www.waldenbiosciences.com.

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