NEWS RELEASE

Novome Biotechnologies Initiates Phase 1/2a Study to Evaluate Therapeutically Engineered Bacteria for the Treatment of Enteric Hyperoxaluria

- NOV-001 is the first therapeutically engineered colonizing gut bacteria to be evaluated in humans -

- Phase 1 results anticipated in 2021 and Phase 2a preliminary efficacy results in 2022 -

SOUTH SAN FRANCISCO, Calif., June 30, 2021 – Novome Biotechnologies, Inc., a biotechnology company engineering first-in-class, living medicines for chronic diseases, today announced the start of a Phase 1 clinical trial of NOV-001, a once-daily, orally-administered Genetically Engineered Microbial Medicine (GEMM) for the potential treatment of enteric hyperoxaluria. Patients with enteric hyperoxaluria are at increased risk of developing kidney stones and, in more severe cases, chronic kidney disease and kidney failure. There are no FDA-approved treatment options for these patients.

"With this significant milestone—starting our first-in-human clinical trial with therapeutically engineered bacteria—we are advancing towards our goal of becoming a leader in the field of living therapeutics," said Blake Wise, Chief Executive Officer of Novome. "We believe that our GEMM cell therapies hold tremendous potential for patients across a wide range of diseases, including ulcerative colitis and irritable bowel syndrome, in addition to enteric hyperoxaluria. We are eager to see the results of this groundbreaking study and its potential to validate our approach to controllably and safely colonize the human gut with therapeutically engineered bacteria."

The Phase 1 clinical trial to evaluate Novome's first GEMM therapy is being conducted in healthy volunteers with the objective of demonstrating safety, tolerability and strain colonization pharmacodynamics. Phase 1 clinical trial results are anticipated later in 2021, with the potential to then immediately begin the Phase 2a portion of the study, which will be designed to demonstrate preliminary efficacy in patients with enteric hyperoxaluria. Results from the Phase 2a study are anticipated in 2022.

"There are many talented individuals at Novome whose teamwork has been essential to advancing NOV-001 into the clinic and to building the GEMMs platform. Their significant contributions will allow Novome to rapidly demonstrate proof-of-concept for our GEMMs platform technology, and to generate clinical data in people with enteric hyperoxaluria next year," said Lachy McLean, Chief Medical Officer of Novome. "For people living with enteric hyperoxaluria, there is a tremendous need to reduce high urinary oxalate levels that are associated with recurrent kidney stones and progressive kidney failure. There are currently no FDA-approved therapies to reduce urine oxalate excretion and we are excited about the potential for NOV-001 to address this high unmet need."

About NOV-001

NOV-001, Novome's first clinical candidate, is an investigational combination product composed of NB1000S, a recombinant live biotherapeutic product, and NB2000P, a botanically derived polysaccharide. Preclinical studies of NOV-001 showed consistent and robust reduction in urine oxalate levels in multiple animal models of disease. The Company believes that NOV-001 will enable controlled colonization of the gut with a strain of *Bacteroides* engineered with a precise metabolic pathway to efficiently degrade oxalate in the gastrointestinal (GI) tract and decrease the risk of progressive kidney damage and kidney stone formation.

About the Clinical Trial

The Phase 1/2a clinical trial is designed to evaluate NOV-001 in healthy volunteers and patients with enteric hyperoxaluria. The first stage of the study, Phase 1, is a prospective, adaptive, Phase 1, first-in-human, randomized, controlled study evaluating the safety, tolerability and strain colonization pharmacodynamics of NOV-001 in adult healthy volunteers. The second stage of the study, Phase 2a, is a prospective, randomized, single-blinded, placebo-controlled study of the safety, tolerability and early efficacy in patients with enteric hyperoxaluria. More information on this study can be found at https://clinicaltrials.gov under the study ID NCT04909723.

About Enteric Hyperoxaluria

Hyperoxaluria is a metabolic disorder characterized by significantly elevated urinary oxalate levels. It is often associated with kidney stones, chronic kidney disease (CKD) and other serious kidney diseases. Enteric hyperoxaluria results from underlying chronic GI disorders, such as bariatric surgery or inflammatory bowel disease, that cause increased absorption of dietary oxalate, which is present in many healthy foods. There are approximately 250,000 patients in the United States with enteric hyperoxaluria and no approved therapies (Source: Kidney Week 2019, Prevalence of Kidney Stones in Patients With Enteric Disorders, G.E. Tasian et al.)

About Novome

Novome Biotechnologies, Inc. is a biotechnology company developing engineered cellular therapies for the gut to treat chronic diseases. The Company has developed the first platform for the controlled colonization of the gut with engineered bacteria to deliver targeted therapeutic cargos and functions, enabling first-in-class living therapeutics: Genetically Engineered Microbial Medicines (GEMMs). Novome is utilizing its proprietary GEMMs platform in its lead program in enteric hyperoxaluria, which is focused on the development of a therapeutic strain of bacteria that degrades oxalate to decrease the risk of kidney stone formation. Efforts are also directed toward advancing pipeline indications in ulcerative colitis, irritable bowel syndrome and immuno-oncology. For more information, please visit the Novome Biotechnologies website at https://novomebio.com/

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