NEWS RELEASE

Novome Biotechnologies Reports Positive Results from a Phase 1 Study of NOV-001

- Orally-administered Genetically Engineered Microbial Medicine (GEMM) was safe and well tolerated and demonstrated dose-dependent strain engraftment in healthy volunteers -

- Results provide proof-of-concept for Novome's approach to controllably and safely colonize the human gut with an engineered cell therapy -

- Patient screening initiated for Phase 2a study in enteric hyperoxaluria -

SOUTH SAN FRANCISCO, Calif., November 17, 2021 – Novome Biotechnologies, Inc., a clinical-stage biotechnology company developing engineered cellular therapies for the gut, today announced positive results from a Phase 1 study of orally-administered NOV-001 in healthy volunteers. The Phase 1 study demonstrated the ability to safely colonize the human gut with a therapeutically engineered microbe and control its abundance via once-daily dosing of a prebiotic control molecule. Based on these results, Novome intends to commence a Phase 2a study to evaluate preliminary efficacy in patients with enteric hyperoxaluria.

Patients with enteric hyperoxaluria have chronically elevated levels of oxalate in their urine that puts them at increased risk of developing kidney stones and, in more severe cases, chronic kidney disease and kidney failure.

"The successful completion of this first-in-human study is an important step for Novome—it both advances our enteric hyperoxaluria program to Phase 2 and provides strong support for the broad potential of Novome's novel GEMMs platform," said Blake Wise, CEO of Novome. "This groundbreaking study validates Novome's approach to controllably and safely engraft a therapeutically engineered microbe into the human gut. We plan to build on this momentum and advance a pipeline of GEMM candidates to tackle a wide range of diseases."

NOV-001 is a first-of-its-kind combination product made up of NB1000S, a proprietary microbial strain that Novome genetically engineered to degrade oxalate, and NB2000P, a seaweed-derived prebiotic polysaccharide, which acts as a privileged carbon source for NB1000S. In the Phase 1 study, the dose of NB2000P was modified within adaptive groups to tune the abundance of NB1000S in the gut. To date, 24 subjects enrolled in the study have received NOV-001 with variable doses of NB2000P between 0.5g/day and 10g/day for 14 days and a single $1x10^9$ colony forming units (CFU) dose of NB1000S. Topline results are summarized below.

Strain Engraftment

- NOV-001 produced high levels of engraftment of NB1000S in the gastrointestinal tract;
  - NB1000S abundance, as determined by periodic stool sampling, was dependent on the dose of NB2000P administered

  - At the highest dose of NB2000P, NB1000S was present at an average of 10^{10} cells per gram of stool, representing approximately 5 percent of the total microbial load in the gastrointestinal tract
- NOV-001 appears to be minimally-disruptive to the native gut microbiota, with the diversity of subjects' flora well-maintained as measured by metagenomic sequencing; and
- When NB2000P dosing was stopped, NB1000S was generally observed to wash out of the gut to below detection limits.

Safety and Tolerability

- NOV-001 was shown to be safe and well tolerated;
- Most adverse events reported were mild (Grade 1);
- No serious adverse events were reported as related to study medication; and
- No subjects required dose adjustment or left the study due to safety events.

"These first-in-human strain engraftment results combined with our nonclinical models of enteric hyperoxaluria, are promising for the future development of NOV-001, our first clinical-stage product candidate. We are optimistic about the potential for NOV-001 to effectively reduce urinary oxalate, high levels of which are associated with recurrent kidney stones and progressive kidney failure," said Dr. Lachy McLean, Novome's Chief Medical Officer. "We look forward to reporting clinical data next year from the Phase 2a study in patients with enteric hyperoxaluria."

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, reported today, 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 NOV-001

NOV-001 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 engraftment of the gut with a microbial strain engineered to efficiently degrade oxalate in the GI tract in order to decrease the risk of progressive kidney damage and kidney stone formation.

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 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 there are no FDA-approved therapies (Source: Kidney Week 2019, Prevalence of Kidney Stones in Patients With Enteric Disorders, G.E. Tasian et al.).

About Novome

Novome Biotechnologies is a clinical-stage 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 inflammatory bowel disease, irritable bowel syndrome and immuno-oncology. For more information, please visit the Novome Biotechnologies website at https://novomebio.com/

#

Source: Novome Biotechnologies, Inc.

Media Contact:
Denise Powell
denise@redhousecomms.com

Follow us on Linkedin: Novome Biotechnologies
Follow us on Twitter: @NovomeBio