Gelesis Announces First U.S. Patient Enrolled in Pivotal Gelesis100 Weight-Loss Study

Company granted U.S. composition of matter patent for Gelesis' technology

BOSTON, Massachusetts, April 26, 2016 -- Gelesis, a biotechnology company focused on the development of first-in-class products to safely induce weight loss and improve glycemic control, today announced the first patient enrolled from the United States (U.S.) in its pivotal GLOW (Gelesis Loss Of Weight) study. GLOW will assess the long-term safety and efficacy of Gelesis100, a novel oral capsulated device designed to achieve weight loss in adults who are overweight or have obesity, including those with prediabetes and type 2 diabetes. GLOW was initiated in November 2014 and has been ongoing at nine clinical trial sites across four European countries, where 125 patients have completed treatment.

The company also announced the allowance of a composition of matter patent from the U.S. Patent and Trademark Office (USPTO) for Gelesis' technology through 2032.

The Gelesis100 capsule contains small hydrogel particles that, when taken with water ahead of a meal, is designed to employ multiple mechanisms of action along the gastrointestinal (GI) tract to induce weight loss and improve glycemic control. In a three-month proof-of-concept study, Gelesis100 demonstrated statistically significant weight loss and improvement of glycemic control in adults who are overweight or have obesity, especially in those with prediabetes. GLOW will study the impact of Gelesis100 in achieving weight loss and glycemic control over a six-month time period and in a broader patient population, including those who have type 2 diabetes, across 32 sites in the U.S., Canada and Europe.

GLOW is a randomized, double-blind, placebo-controlled, parallel-group study of 460 adults who are overweight or have obesity (Body Mass Index: 27-40) between the ages of 22 to 65 years, including those with prediabetes and type 2 diabetes. The study's primary endpoints are placebo-adjusted change in total body weight from baseline to end of treatment, and percent of individuals with at least five percent weight loss. The secondary endpoints include changes in key glycemic control parameters.

"There is a great need for new, safe therapeutic options that facilitate both weight loss and glycemic control, especially in people with prediabetes," said Gelesis Scientific Advisory Board member Caroline Apovian, M.D., Professor of Medicine and Pediatrics at Boston University School of Medicine. "We are excited to study the Gelesis product in the U.S. with some of the top clinicians in this field."

Gelesis received positive confirmation from the U.S. Food and Drug Administration (FDA) in July 2015 that GLOW received a Non-Significant Risk (NSR) medical device study designation, which allowed the Company to expand the study to the U.S. The FDA's NSR designation applies to devices that are generally considered to be low risk based on their intended use in the study. Examples of NSR devices include daily wear contact lenses, dental filling materials and jaundice monitors for infants.

"Enrolling our first patient in the U.S. is an important milestone as we advance this novel therapeutic as a potentially effective, non-invasive weight-loss treatment for adults who are overweight or have obesity," said Hassan Heshmati, M.D., Chief Medical Officer of Gelesis. "More than two-thirds of U.S. adults are overweight or obese, so there is a critical need for new approaches that can help these individuals achieve and maintain a healthy weight."

Gelesis recently received a Notice of Allowance from the USPTO for a patent application covering composition of matter. The issued patent will have a term extending to 2032. Gelesis already owns two additional patent families with granted or allowed patents in the US, Europe, Canada, Australia, Japan, Russia, Mexico, China and Hong Kong. Several other patent families are in different stages of prosecution.

About Gelesis100

Gelesis100 is an orally administered capsule containing small hydrogel particles designed to employ multiple mechanisms of action along the gastrointestinal (GI) tract to induce weight loss and improve glycemic control. The hydrogel particles are synthesized through Gelesis' multi-step, proprietary process using starting materials which are considered Generally Recognized As Safe (GRAS) by the FDA and commonly used in the food industry.

Gelesis100 capsules are taken with water prior to a meal, after which the hydrogel particles are released from the capsules in the stomach and rapidly absorb water, hydrating to approximately 100 times their original size. The hydrogel particles mix homogeneously with food and travel through the GI tract, potentially inducing satiety and improving glycemic control. Once in the large intestine, the particles release most of the water, which is reabsorbed by the body. The microscopic degraded particles are then safely eliminated by the body in the same manner as food.

About Gelesis

Gelesis is focused on the development of novel therapies designed to induce weight loss and improve glycemic control in people who are overweight or have obesity, including those with prediabetes and type 2 diabetes. Gelesis100, one of the company's product candidates and a first-in-class therapeutic, is currently being evaluated in a six-month pivotal study. Gelesis is also developing Gelesis200, created from the same proprietary technology platform as Gelesis100, as a product optimized to induce weight loss and improve glycemic control in patients with prediabetes and type 2 diabetes.

The Gelesis executive and advisory team includes leading experts in obesity and its related comorbidities, clinical research and development, and advanced biomaterials, including Caroline Apovian, M.D., Professor of Medicine and Pediatrics at Boston University School of Medicine; Louis J. Aronne, M.D., FACP, Director of the Comprehensive Weight Control Program at Weill Cornell Medicine, who also holds equity in Gelesis; Arne Astrup, M.D., Head of Department of Nutrition, Exercise and Sports at University of Copenhagen; Ken Fujioka, M.D., Director of the Nutrition and Metabolic Research Center and the Center for Weight Management at the Scripps Clinic; Allan Geliebter, Ph.D., Senior Attending Psychologist, St. Luke's-Roosevelt Hospital; James Hill, Ph.D., Professor of Medicine and Pediatrics, University of Colorado; Lee M. Kaplan, M.D., Ph.D., Director of the Obesity, Metabolism and Nutrition Institute at Massachusetts General Hospital; Bennett Shapiro, M.D., Co-founder and Non-Executive Director at PureTech and former Executive Vice President of Research for Merck; and Angelo Tremblay, Ph.D., Professor, Department of Kinesiology at Laval University.

Gelesis investors include Cormorant Asset Management, PureTech Health PLC (LSE: PRTC), Invesco Asset Management, the Priztker/Vlock Family Office and other prominent biotech and finance investors.

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