Gelesis Announces Positive Safety Data from First-In-Human Study of Second Product Candidate, Gelesis200

Novel product for weight loss and glycemic control in patients with type 2 diabetes proven safe and well-tolerated

BOSTON, Massachusetts, May 3, 2016 -- Gelesis, a biotechnology company focused on developing first-in-class products to safely induce weight loss and improve glycemic control, today announced positive results from a first-in-human study of Gelesis200, its next-generation product designed for patients with type 2 diabetes. Gelesis200 is a novel oral capsulated device that seeks to induce weight loss and improve glycemic control in patients with type 2 diabetes.

Results from the study showed Gelesis200 was generally well-tolerated. No serious adverse events (AEs) were reported, and the total number of AEs reported in the active treatment arms was comparable to the total number of AEs reported in the placebo arms.

"We are pleased with the safety and tolerability Gelesis200 demonstrated in this first-in-human study," said Hassan Heshmati, M.D., Chief Medical Officer of Gelesis. "Our next step will be to assess Gelesis200 in a three-month proof-of-concept study - expected to read out in the first half of 2017 - with the goal of ultimately offering a novel weight management and glycemic control product for patients with type 2 diabetes."

The primary objective of this single-center, randomized, double-blind, placebo-controlled, two-cohort, four-arm, crossover study was to evaluate the safety and tolerability of Gelesis200 following two or three administrations of 2.10 g in a single day – before breakfast and lunch or before breakfast, lunch and dinner – in adults who are overweight or have obesity but are otherwise considered healthy. The study was conducted in 24 male subjects with body mass indexes ranging from 28 to 33.

The data also indicated that administering Gelesis200 three times in a single day did not result in more AEs than administering it two times in a single day. Further, the timing of administration of Gelesis200 (10 minutes versus 30 minutes before a meal) did not affect the number of AEs.

The majority of AEs reported in the active treatment arms were mild, the most common of which were gastrointestinal-related and headache.

About Gelesis200

Gelesis200 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 in patients with type 2 diabetes. The hydrogel particles are synthesized through Gelesis' multi-step, proprietary process using starting materials that are considered Generally Recognized as Safe (GRAS) by the U.S. Food and Drug Administration and commonly used in the food industry.

Gelesis200 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 85 times their

original size to generate a feeling of fullness. Gelesis200's high elastic response and accelerated absorption mechanism makes it a prime candidate for potentially achieving glycemic control in people with type 2 diabetes through multiple mechanisms of action through the GI. Once in the large intestine, the particles release most of the water, which is reabsorbed by the body. The microscopic degraded particles are then eliminated by the body in the same manner as food.

About Gelesis

Gelesis is focused on the development of novel therapies 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 type 2 diabetes.

The Gelesis executive and advisory teams comprise 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 Pritzker/Vlock Family Office, and other prominent biotech and finance investors.

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