



## PureTech Health's Gelesis Reports Significant Weight Loss with Excellent Safety Profile in Pivotal Study with Gelesis100

September 25, 2017

PureTech Health plc ("PureTech", LSE: PRTC), an advanced, clinical-stage biopharmaceutical company, is pleased to note that Gelesis, an affiliate of PureTech Health, today announced topline results from the pivotal weight loss study (GLOW) of one of its product candidates, Gelesis100.

The study achieved and exceeded one of two co-primary endpoints with 58% of adults in the Gelesis100 treatment arm achieving 5% or more weight loss. Additionally, almost twice as many adults on Gelesis100 lost 10% or more of their body weight compared to the placebo group ( $p=0.027$ ). Although the study did not meet the other co-primary endpoint of 3% mean difference from placebo, the Gelesis100-treated adults showed statistically significant weight loss vs. placebo ( $p=0.0032$ ). Gelesis will present the full study results at a scientific conference and intends to move ahead with submission for approvals after getting input from regulatory authorities. An ongoing 6-month extension study will provide additional safety and efficacy results out to one year.

Eric Elenko, PhD, Chief of Research and Strategy at PureTech Health, said: "We're happy with the results of this study, which showed on average that 6 out of 10 of participants treated with Gelesis100 lost 5% or more of their total body weight and 20% of the treated adults lost 10% or more of their weight. Coupled with the excellent safety profile, and the efficacy and safety data across previous Gelesis clinical studies, these results provide a strong package that the Gelesis team looks forward to sharing with regulatory authorities. The key opinion leaders on our Scientific Advisory Board, who assisted Gelesis in interpreting the results, were excited about the potential for Gelesis100 as a new approach for their patients struggling with weight loss."

This announcement contains inside information for the purposes of Article 7 of Regulation (EU) 596/2014.

The full text of the announcement from Gelesis is as follows:

### Gelesis100 Achieves Significant Weight Loss with Excellent Safety Profile in Pivotal Study

58% of treated adults lost 5% or more of their weight over six months, and almost twice as many individuals achieved 10% or more weight loss compared to placebo

Study exceeded one of two co-primary endpoints and Company plans to move forward with submission for regulatory approvals

**BOSTON, Massachusetts, September 25, 2017** – Gelesis, a biotechnology company developing first-in-class therapies to treat chronic diseases related to the gastrointestinal (GI) pathway, today announced topline results from a pivotal weight loss study of one of its product candidates, Gelesis100. The study exceeded one of the two co-primary endpoints with 58% of adults in the Gelesis100 treatment arm achieving clinically meaningful weight loss of 5% or more during the study. The percent of patients who achieved 5% or more weight loss was statistically significant compared to placebo (58% vs. 42%,  $p=0.0028$ ). Additionally, almost twice as many adults on Gelesis100 lost 10% or more of their body weight compared to the placebo group (20% vs. 12%,  $p=0.027$ ). Although the study did not meet the other co-primary endpoint of 3% mean difference from placebo, the Gelesis100-treated adults showed statistically significant weight loss vs. placebo ( $p=0.0032$ ). Gelesis100 showed no increased safety risk, no serious adverse events, and a lower dropout rate compared to placebo. Full results will be presented at a scientific conference and will be submitted for publication in a peer-reviewed medical journal. Given the demonstrated weight loss and safety profile, Gelesis plans to discuss filing with regulatory authorities and if they are supportive, plans to file for approval.

"Based on these results, Gelesis100 could potentially be the treatment we've been missing for the patients who need it most. Current interventional approaches to weight loss are often invasive and/or have serious side effects," said Frank L. Greenway, MD, a leading expert in the field of weight research and the principal investigator in the GLOW study. "As a physician, knowing that the majority of my patients could achieve clinically meaningful weight loss without some of the safety trade-offs makes me excited about this potential new approach."

The Gelesis Loss Of Weight (GLOW) Study was a randomised, double-blind, placebo-controlled, parallel-group study enrolling 436 adults with a body mass index (BMI)  $\geq 27$  and  $\leq 40$  kg/m<sup>2</sup>, including those with prediabetes or type 2 diabetes. The 6-month study compared a 2.25 g dose of Gelesis100, administered twice daily, to placebo and was conducted at 33 sites across the United States and several European countries. Both the Gelesis100 and placebo arms also included a hypocaloric diet and daily physical activity. An ongoing 6-month extension study will provide additional safety and efficacy results out to one year.

"We are pleased with the results of the study, particularly that 6 out of 10 adults on Gelesis100 achieved 5% or more weight loss within 6 months, and 20% of adults on Gelesis100 reached 10% or more weight loss," said Hassan M. Heshmati, MD, Chief Medical Officer of Gelesis. "Based on this and our other studies, we look forward to sharing the full data package with regulatory authorities and to potentially bringing Gelesis100 to patients."

"Feedback from physicians and patients has consistently highlighted the attractiveness of this new oral, non-systemic approach to weight loss," commented David Pass, PharmD, Chief Operating Officer and Head of Commercial for Gelesis. "We continue to build our commercial capabilities, and we are working to bring Gelesis100 to the millions of people around the world who are struggling with their weight."

### About Gelesis100

Gelesis100 is a new approach to weight loss that is designed to employ multiple mechanisms of action along the GI tract to promote satiety and induce weight loss. Gelesis100 is non-systemic and administered orally in capsules containing small hydrogel particles, which are made from two naturally-

derived ingredients that compose a novel 3D matrix. The novel hydrogel is manufactured through Gelesis' multi-step, proprietary process and protected by 9 families of patents, several of which have already been allowed or issued in major markets.

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. Gelesis100 is designed to mix homogeneously with food and travel through the GI tract, inducing satiety, reducing hunger, and causing weight loss. Once in the large intestine, Gelesis100 releases most of the water, which is reabsorbed by the body. The small gel particles pass through the body without being absorbed and are safely eliminated in the same manner as food.

Gelesis100 has been studied in more than 500 patients across five clinical studies throughout the United States, Canada, and Europe and has shown weight loss, increased satiety, reduced hunger, and a consistently strong safety profile.

#### **About Gelesis**

Gelesis is developing a novel mechanobiology platform to treat obesity and other chronic diseases related to the GI pathway. Gelesis' proprietary approach leverages rheological properties to act mechanically in the GI pathway to potentially alter the course of chronic diseases safely and effectively. In Q3 2017, Gelesis completed a pivotal trial for weight loss evaluating its lead product candidate Gelesis100. Additionally, Gelesis recently initiated a proof-of-concept study for its second candidate, Gelesis200 (GS200), which is optimised for weight loss and glycaemic control in patients with type 2 diabetes and prediabetes. New hydrogel compositions based on the Gelesis mechanobiology platform technology are also being explored through an expanded pipeline with preclinical and clinical studies in other GI-related conditions such as non-alcoholic fatty liver disease (NAFLD), non-alcoholic steatohepatitis (NASH) and intestinal mucositis.

The Gelesis executive and advisory team includes some of the world's leading experts in obesity, chronic disease research, and clinical development, as well as material science innovators, commercialisation experts, and entrepreneurs. Gelesis is an affiliate of PureTech Health (PRTC.L), an advanced, clinical-stage biopharmaceutical company. For more information, visit [www.gelesis.com](http://www.gelesis.com) or connect with us on Twitter @GelesisInc.

#### **About PureTech Health**

PureTech Health (PureTech Health plc, PRTC.L) is an advanced, clinical-stage biopharmaceutical company developing novel medicines targeting serious diseases that result from dysfunctions in the nervous, immune, and gastrointestinal systems (brain-immune-gut or the "BIG" axis), which together represent the adaptive human systems. PureTech Health is at the forefront of understanding and addressing the biological processes and crosstalk associated with the BIG axis. By harnessing this emerging field of human biology, the Company is pioneering new categories of medicine with the potential to have great impact on people with serious diseases. PureTech Health is advancing a rich pipeline of innovative therapies that includes two pivotal stage programmes, multiple human proof-of-concept studies and a number of early clinical and pre-clinical programmes. PureTech's rich research and development pipeline has been advanced in collaboration with some of the world's leading scientific experts, who along with PureTech's team of biopharma pioneers, entrepreneurs and seasoned Board, identify, invent, and clinically de-risk new medicines. With this experienced team pursuing cutting edge science, PureTech Health is building the biopharma company of the future focused on improving and extending the lives of people with serious disease. For more information, visit [www.puretechhealth.com](http://www.puretechhealth.com) or connect with us on Twitter @puretechh.

#### **Forward Looking Statement**

This press release contains statements that are or may be forward-looking statements, including statements that relate to the company's future prospects, developments and strategies. The forward-looking statements are based on current expectations and are subject to known and unknown risks and uncertainties that could cause actual results, performance and achievements to differ materially from current expectations, including, but not limited to, those risks and uncertainties described in the risk factors included in the regulatory filings for PureTech Health plc. These forward-looking statements are based on assumptions regarding the present and future business strategies of the company and the environment in which it will operate in the future. Each forward-looking statement speaks only as at the date of this press release. Except as required by law and regulatory requirements, neither the company nor any other party intends to update or revise these forward-looking statements, whether as a result of new information, future events or otherwise.