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PureTech Health plc

PureTech Health's Gelesis Announces Last Patient Visit in the Pivotal Gelesis100 Weight-Loss Study

PureTech Health plc ("PureTech", LSE: PRTC), an advanced, clinical-stage biopharmaceutical company, is pleased to note that Gelesis, Inc. (a subsidiary of PureTech Health) has completed treatment of the final patient in the pivotal GLOW (Gelesis Loss Of Weight) Study. GLOW was designed to assess the long-term efficacy and safety of lead product candidate Gelesis100 over a six-month period across a broad patient population. Results from this registration-enabling trial are anticipated in Q3 2017.

Gelesis has also enrolled its first European patient in the ongoing LIGHT-UP study with its second product candidate, Gelesis200, for weight loss and glycaemic control. LIGHT-UP will enrol individuals across the United States, Canada, and Europe who are overweight or have obesity and also have prediabetes or metformin-treated type 2 diabetes.

Dr. Bharatt Chowrira, President and Chief of Business and Strategy at PureTech Health, said: "We're delighted to have achieved these important milestones and to expand the breadth of the Gelesis platform. As a result of new, preclinical research and the pioneering work of Gelesis in this emerging field of mechanobiology, we are also planning or initiating pilot studies across a number of additional indications including early nonalcoholic steatohepatitis (NASH), inflammatory bowel disease (IBD), and other gastrointestinal disorders."

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

Gelesis Announces Last Patient Out in the Pivotal Gelesis100 Weight-Loss Study

Company also expands to Europe its ongoing study of second product candidate, Gelesis200, for weight loss and glycaemic control in people with prediabetes or type 2 diabetes

BOSTON, Massachusetts, July 12, 2017 -- [Gelesis, Inc.](#), a biotechnology company developing a novel category of therapies to safely induce weight loss, improve glycaemic control, and treat other chronic diseases related to the gastrointestinal (GI) pathway, is pleased to report today that the last patient has completed treatment in the pivotal GLOW (Gelesis Loss Of Weight) Study. The GLOW study was designed to assess the long-term efficacy and safety of lead product candidate Gelesis100 over a six-month period across a broad patient population. The company has also enrolled its first European patient in the ongoing LIGHT-UP study with its second product candidate, Gelesis200, for weight loss and glycaemic control. The study will enrol individuals who are overweight or have obesity and also have prediabetes or metformin-treated type 2 diabetes at more than 30 sites across the United States, Canada, and Europe.

"We're pleased to have reached these two milestones for Gelesis as we continue to progress our platform technology and expand our pipeline," said Hassan Heshmati MD, Chief Medical Officer of Gelesis. "We're also continuing to establish a body of data around our platform technology, as we

explore additional GI-related conditions such as nonalcoholic fatty liver disease (NAFLD), nonalcoholic steatohepatitis (NASH), and inflammatory bowel disease (IBD).”

Further investigation of the Gelesis mechanism has led to an international collaboration with leading obesity and nutrition experts and new insights about how people with prediabetes respond to different types of diets, [published in the *American Journal of Clinical Nutrition*](#). “We are learning a remarkable amount about the potential positive impact on local inflammation and glycaemic parameters through our unique hydrogel system that is at the forefront of mechanobiology,” added Elaine Chiquette, Pharm.D., EVP Head of Science, Gelesis. “This emerging [field](#) at the interface of biology and engineering focuses on how cells sense and respond to mechanical stimuli and is helping us to unlock insights into the gut-brain-inflammation axis.”

About Gelesis100 and Gelesis200

Gelesis100 is a pivotal-stage product candidate for weight loss and glycaemic control, which has demonstrated statistically significant weight loss, reduced hunger, increased satiety and strong safety in previous clinical studies. Gelesis200 is a second product candidate that has been engineered for rapid hydration with significantly higher elasticity to enhance glycaemic control and weight loss for patients who have pre-diabetes or type 2 diabetes. A proof-of-concept clinical study with Gelesis200 (LIGHT-UP) has been initiated for weight loss and glycaemic control in people with prediabetes or type 2 diabetes. The results from this study are expected mid-2018.

Both Gelesis100 and Gelesis200 are orally – administered capsules containing small hydrogel particles made by cross-linking two naturally occurring food ingredients to generate novel compositions that are expected to be safe and well tolerated. Gelesis product candidates are designed to employ multiple mechanisms of action that leverage [mechanotransduction](#) along the gastrointestinal (GI) tract to induce weight loss and improve glycaemic control. The hydrogel particles swell and shrink in different parts of the GI system, mix homogeneously with food, travel through the GI tract, and – once in the large intestines – release most of the water, which is reabsorbed by the body. The small hydrogel particles are then safely eliminated by the body in the same manner as food.

To our knowledge, Gelesis’ novel hydrogels are the only super absorbents made from materials which are considered Generally Recognised As Safe (GRAS) by the U.S. Food and Drug Administration (FDA) and commonly used in foods. Gelesis also received positive confirmation from the FDA that GLOW is a nonsignificant risk (NSR) device study. Gelesis holds 11 families of patents, several of which have already been allowed or issued in major markets. Most recently, Gelesis received a Notice of Allowance from Japan Patent Office (JPO) on Patent No. 2014-514632 covering composition of matter for Gelesis100.

About Gelesis

Gelesis is developing a novel hydrogel platform to treat obesity and other chronic diseases related to the gastrointestinal (GI) pathway. Gelesis’ proprietary approach acts mechanically in the GI system to potentially alter the course of chronic diseases safely and effectively. Gelesis is currently evaluating its lead product candidate, Gelesis100, in a pivotal trial for weight loss, which is expected to read out in Q3 2017. Additionally, Gelesis recently initiated a proof-of-concept study for its second candidate, Gelesis200, which is optimised for weight loss and glycaemic control in patients with type 2 diabetes

and pre-diabetes. New hydrogel compositions based on the Gelesis platform are also being explored in preclinical and pilot studies in other GI-related conditions such as nonalcoholic fatty liver disease (NAFLD), nonalcoholic steatohepatitis (NASH), and inflammatory bowel disease (IBD).

The Gelesis executive and advisory team includes some of the world's leading experts in obesity research and clinical development, innovators in material science, and entrepreneurs. Gelesis was co-founded by PureTech Health (PRTC.L), an advanced, clinical-stage biopharmaceutical company (www.puretechhealth.com).

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 immune, nervous, and gastro-intestinal systems by intervening early and addressing the underlying pathophysiology of disease. The Company is advancing a rich pipeline that includes two pivotal or registration studies expected to read out in 2017, multiple human proof-of-concept studies, and a number of early clinical and pre-clinical programs. PureTech Health's growing research and development pipeline has been developed in collaboration with some of the world's leading scientific experts, who along with PureTech's experienced team and a stellar Board identify, analyse and advance very selectively the opportunities the Company believes hold the most promise for patients. This experienced and engaged team places PureTech Health at the forefront of ground-breaking science and technological innovation and leads the Company between and beyond existing disciplines. For more information, visit www.puretechhealth.com or connect with us on Twitter [@puretechh](https://twitter.com/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.

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