



## PureTech Founded Entity Gelesis Presents Plenity® Efficacy and Safety Data at the European and International Congress on Obesity 2020

September 4, 2020

*Subgroup analysis showed adults reaching BMI <27 kg/m<sup>2</sup> on average lost 13.5% of total body weight during the trial*

*Plenity (Gelesis100) is an orally administered, non-stimulant, non-systemic aid in weight management based on proprietary hydrogel technology with a highly favourable safety and efficacy profile demonstrated in clinical studies*

*Plenity is currently available in the US in limited release with a full launch in 2021*

[PureTech Health plc](#) (LSE: PRTC) ("PureTech" or the "Company"), a clinical-stage biotherapeutics company dedicated to discovering, developing and commercialising highly differentiated medicines for devastating diseases, is pleased to note that its Founded Entity, Gelesis, today announced it will deliver one oral presentation and two poster presentations showcasing notable efficacy data for Plenity® (Gelesis100) at the European and International Congress on Obesity (ECO-ICO 2020).

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

### **Plenity® Efficacy and Safety Data to be Presented at the European and International Congress on Obesity 2020**

*Plenity (Gelesis100) is an orally administered, non-stimulant, non-systemic aid in weight management based on proprietary hydrogel technology with a highly favourable safety and efficacy profile demonstrated in clinical studies*

*Plenity is currently available in the US in limited release with a full launch in 2021*

**Boston – September 4, 2020** – Gelesis, a biotechnology company developing a novel hydrogel platform technology to treat overweight, obesity and other chronic metabolic diseases, announced it will deliver one oral presentation and two poster presentations showcasing notable efficacy data for Plenity® (Gelesis100) at the European and International Congress on Obesity (ECO-ICO 2020).

Plenity is an oral, non-systemic therapeutic cleared by the FDA as an aid for weight management in adults with a BMI of 25–40 kg/m<sup>2</sup>, when used in conjunction with diet and exercise. The company also received a CE Mark, which enables the marketing of Plenity in Europe. The novel treatment is administered in the form of capsules taken with water before lunch and dinner. The capsules release thousands of particles that rapidly absorb water in the stomach, creating small individual gel pieces with the elasticity and firmness of plant-based foods (e.g., vegetables) without caloric value. The hydrogel contributes to a feeling of fullness and induces satiety. Plenity is currently available in the US in limited release with a full launch in 2021.

"Plenity presents both patients and clinicians with the opportunity for early intervention progression," said Ken Fujioka, MD, endocrinology researcher at Scripps Clinic and scientific advisor to Gelesis. "Based on the weight loss achieved in patients lower in the BMI spectrum, this is a scientifically-validated option for patients looking to lose as little as 10-15 pounds, or more."

### **Details of the data presentations are as follows:**

- Friday, September 4<sup>th</sup>, 7:40AM EDT: Safety of Gelesis100 in Subjects Who Reached a Body Mass Index Below 27 kg/m<sup>2</sup> in the GLOW Study; presented by Louis J. Aronne, MD, FACP, Sanford I. Weill Professor of Metabolic Research, Weill-Cornell Medical College
- Poster Presentation (EP-459): Safety of Gelesis100 in Overweight or Obesity: Comprehensive Analysis of the GLOW Study; Ken Fujioka, MD, Director of the Nutrition and Metabolic Research Center and the Center for Weight Management, Scripps Clinic
- Poster Presentation (EP-455): Relevance of Intervention with Gelesis100 in Overweight and Mild Obesity: a Subgroup Analysis of the Pivotal GLOW Study; Livio Luzi, MD, Professor of Endocrinology, University of Milan

### **Gelesis Loss Of Weight (GLOW) clinical study**

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 Plenity, administered twice daily, to placebo and was conducted at 33 sites across the United States and several European countries. Both the active and placebo arms also included a hypocaloric diet and daily physical activity. The study had two predefined co-primary endpoints: at least 35% of patients taking Plenity achieving  $\geq 5\%$  weight loss (categorical endpoint) and placebo-adjusted weight loss with a super-superiority margin of 3%. In addition, a prespecified analysis of simple superiority was also performed. The study met and exceeded the predefined categorical endpoint, with 59% of adults in the treatment group achieving weight loss of 5% or greater. The study did not meet the 3% super-superiority endpoint but demonstrated superiority of the Plenity treatment over the placebo group ( $-6.4\%$  vs.  $-4.4\%$ ,  $P=0.0007$ ). Plenity-treated individuals had twice the odds of achieving at least 5% weight loss vs. placebo (adjusted odds ratio [OR]: 2.0,  $P=0.0008$ ). In addition, 26% of the adults who completed the treatment with Plenity were "super-responders," defined as achieving at least 10% weight loss. These super-responders achieved an average of about 14% weight loss or

approximately 30 pounds. The overall incidence of adverse events (AEs) in the Plenity treatment group was no different from placebo. The most common treatment-related adverse events (TRAEs) were gastrointestinal disorders (158 TRAEs in 84 [38%] subjects in the Plenity arm, compared to 105 events in 58 [28%] subjects receiving placebo), infections and infestations (2 events in 2 [1%] subjects with Plenity and 1 event in 1 [1%] subjects with placebo), and musculoskeletal and connective tissue disorders (3 events in 2 [1%] subjects with Plenity and 0 in 0 [0%] subjects with placebo). There were no serious adverse events (SAE) in the Plenity treatment group, whereas there was one (1) SAE in the placebo treatment group.

### **About Plenity®**

Plenity is an oral, non-systemic, superabsorbent hydrogel which has received FDA clearance as an aid in weight management in overweight and obese adults with a BMI of 25–40 kg/m<sup>2</sup>, when used in conjunction with diet and exercise. Gelesis has also received approval to market Plenity in the European Economic Area. Plenity is made by cross-linking two naturally derived building blocks, modified cellulose and citric acid, that create a three-dimensional matrix. Plenity particles rapidly absorb water in the stomach and homogeneously mix with ingested foods. Rather than forming one large mass, it creates thousands of small individual gel pieces with the elasticity and firmness of solid plant-based foods (e.g., vegetables) without caloric value. The Plenity hydrogel increases the volume and elasticity of the stomach and small intestine contents and induces a feeling of fullness and satiety. Once it arrives in the large intestine, the hydrogel is partially broken down by enzymes and loses its three-dimensional structure along with most of its absorption capacity. The released water is reabsorbed in the large intestine, and the remaining cellulosic material is eliminated through the body's natural digestive processes. Plenity is considered a medical device because it achieves its primary intended purpose through mechanical modes of action consistent with mechanobiology constructs. For more information, visit [myplenity.com](http://myplenity.com).

### **Important Safety Information**

- Plenity is contraindicated in patients who are pregnant or are allergic to cellulose, citric acid, sodium stearyl fumarate, gelatin, or titanium dioxide
- Plenity may alter the absorption of medications. Read Sections 6 and 8.3 of the Instructions for Use carefully
- Avoid use in patients with: esophageal anatomic anomalies, including webs, diverticuli, and rings; suspected strictures (such as patients with Crohn's disease); and complications from prior gastrointestinal (GI) surgery that could affect GI transit and motility
- Use with caution in patients with active gastrointestinal conditions such as gastro-esophageal reflux disease (GERD), ulcers, or heartburn
- The overall incidence of AEs in the Plenity group was no different than the placebo group
- The most common side effects were diarrhea, distended abdomen, infrequent bowel movements, and flatulence.

For the safe and proper use of Plenity, refer to the [US Instructions for Use](#) or the [EU Instructions for Use](#).

### **About Gelesis**

Gelesis is developing a novel hydrogel platform technology to treat overweight and obesity and chronic diseases related to the GI pathway. Gelesis' proprietary approach is designed to act mechanically in the GI pathway to potentially alter the course of certain chronic diseases. In April 2019, Gelesis received FDA clearance for its lead product candidate, Plenity®, as an aid for weight management in overweight and obese adults with a Body Mass Index (BMI) of 25-40 kg/m<sup>2</sup>, when used in conjunction with diet and exercise. It was also granted a CE Mark, which allows Gelesis to market Plenity in the European Economic Area. Plenity is currently available in limited release in the US. Additionally, Gelesis is developing its second investigational candidate, Gelesis200, a hydrogel optimised for weight loss and glycaemic control in patients with type 2 diabetes and prediabetes. Novel hydrogel mechanotherapeutics based on the Gelesis platform technology are also being advanced in other GI inflammatory conditions, such as non-alcoholic steatohepatitis (NASH) and functional constipation. For more information, visit [gelesis.com](http://gelesis.com) or connect with us on Twitter [@GelesisInc](#).

### **About PureTech Health**

PureTech is a clinical-stage biotherapeutics company dedicated to discovering, developing and commercialising highly differentiated medicines for devastating diseases, including intractable cancers, lymphatic and gastrointestinal diseases, central nervous system disorders and inflammatory and immunological diseases, among others. The Company has created a broad and deep pipeline through the expertise of its experienced research and development team and its extensive network of scientists, clinicians and industry leaders. This pipeline, which is being advanced both internally and through PureTech's Founded Entities, is comprised of 24 products and product candidates, including two that have received US Food and Drug Administration (FDA) clearance and European marketing authorisation. All of the underlying programmes and platforms that resulted in this pipeline of product candidates were initially identified or discovered and then advanced by the PureTech team through key validation points based on the Company's unique insights into the biology of the brain, immune and gut, or BIG, systems and the interface between those systems, referred to as the BIG Axis.

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.