



## **PureTech Founded Entity Gelesis Presents Findings on Plenity®-Induced Weight Loss at the American Association of Clinical Endocrinology (AACE) 2021 Annual Virtual Meeting**

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### **PureTech Founded Entity Gelesis Presents Findings on Plenity®-Induced Weight Loss at the American Association of Clinical Endocrinology (AACE) 2021 Annual Virtual Meeting**

*Analysis showed that treatment for weight management with Plenity resulted in NALFD Fibrosis Score Improvement*

*These data support further clinical investigation using Gelesis' superabsorbent hydrogel platform for the potential treatment of metabolic-related liver disease*

*First patient to enroll in a clinical trial leveraging this platform technology for treatment of NASH/NAFLD later this year*

[PureTech Health plc](#) (Nasdaq: PRTC, LSE: PRTC) ("PureTech" or the "Company"), a clinical-stage biotherapeutics company dedicated to discovering, developing and commercializing highly differentiated medicines for devastating diseases, is pleased to note that its Founded Entity, Gelesis, announced today a poster presentation at the American Association of Clinical Endocrinology (AACE) 2021 Annual Virtual Meeting. The post-hoc analysis showed that treatment for weight management with Plenity decreased a marker for liver fibrosis (the NAFLD fibrosis score, or NFS) compared to placebo.

Plenity is a non-systemic oral superabsorbent hydrogel (OSH) that is FDA-cleared to aid in weight management in adults with excess weight or obesity, Body Mass Index (BMI) of 25 to 40 kg/m<sup>2</sup>, when used in conjunction with diet and exercise.

This retrospective analysis of Gelesis' GLOW (Gelesis Loss of Weight) pivotal study assessed the impact of OSH treatment on liver health as measured by the NFS, which is intended to predict the presence of significant fibrosis using common clinical and laboratory values, including age, BMI, diabetes status, AST/ALT ratio, platelet count and serum albumin.

The data presented today support the rationale for conducting further trials to evaluate OSH for the treatment of metabolic-related liver diseases. Gelesis plans to enroll the first patient in a clinical study of its OSH GS300 therapeutic candidate in non-alcoholic steatohepatitis and non-alcoholic fatty liver disease (NASH/NAFLD) by the end of 2021.

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

#### **Post-Hoc Analysis Showed Plenity®-Induced Weight Loss Resulted in NALFD Fibrosis Score Improvement**

*NAFLD Fibrosis Score (NFS) was developed to predict the presence of significant fibrosis using common clinical and laboratory values*

*The findings were presented today at the American Association of Clinical Endocrinology's Annual Meeting*

*These data support further clinical investigation using Gelesis' superabsorbent hydrogel platform for the potential treatment of metabolic-related liver disease. The company plans to enroll its first patient in a clinical trial leveraging this platform technology for the disease later this year*

**Boston, May 27, 2021** - Gelesis, a biotechnology company developing a novel hydrogel platform technology to treat obesity and other chronic metabolic diseases, released today a poster presentation at the American Association of

Clinical Endocrinology's annual meeting. The post-hoc analysis showed that treatment for weight management with Plenity® decreased a marker for liver fibrosis (the NAFLD fibrosis score, or NFS) compared to placebo.

Plenity is a non-systemic oral superabsorbent hydrogel (OSH) that is FDA-cleared to aid in weight management in adults with excess weight or obesity, Body Mass Index (BMI) of 25 to 40 kg/m<sup>2</sup>, when used in conjunction with diet and exercise.

Gelesis' portfolio of non-caloric superabsorbent hydrogels is inspired by the composition and mechanical properties (e.g. firmness) of raw vegetables. They are conveniently administered in capsules taken with water to create a much larger volume of small, non-aggregating hydrogel pieces that become an integrated part of the meals, and act locally in the digestive system.

This retrospective analysis of Gelesis' GLOW (Gelesis Loss of Weight) pivotal study assessed the impact of OSH treatment on liver health as measured by the NFS, which is intended to predict the presence of significant fibrosis using common clinical and laboratory values, including age, BMI, diabetes status, AST/ALT ratio, platelet count and serum albumin.

NFS was calculated at baseline and at 6 months for 317 study participants who had all available data at both timepoints. At baseline, 53.6% of patients receiving Plenity and 53.7% receiving placebo had a moderate or high NFS. At 6 months, fewer patients had moderate or high NFS in the Plenity group (45.2), while there was no change in the placebo group. The absolute numerical change in score was compared between baseline and 6 months, and a statistically significant reduction was observed in NFS within the Plenity group (-.15; p=0.030), but not the placebo group (+0.02; p=0.824). The difference between groups was statistically significant (p=0.043).

"These data further emphasize the need to address pre-obesity with and without comorbidities. Liver health is not always considered with a weight management plan, and yet early intervention may help prevent patients from developing metabolic-related liver disease," said presenting author Dr. Christopher Still, DO, FACP, Medical Director for the Center for Nutrition and Weight Management, and Director for Geisinger Obesity Research Institute at Geisinger Medical Center. Dr. Still also participated in the GLOW study.

The data presented today support further trials of OSH treatment for metabolic-related liver diseases. Gelesis' plans to enroll the first patient in a clinical study of its OSH GS300 in non-alcoholic steatohepatitis and non-alcoholic fatty liver disease, or NASH/NAFLD, by the end of 2021.

### **About Gelesis**

Gelesis is a consumer-centered biotherapeutics company advancing a novel category of treatments for weight management and gut related chronic diseases. Our biomimetic superabsorbent hydrogels are inspired by the composition and mechanical properties (e.g. firmness) of raw vegetables. They are conveniently administered in capsules taken with water to create a much larger volume of small, non-aggregating hydrogel pieces that become an integrated part of the meals, and act locally in the digestive system.

Our portfolio includes Plenity, an FDA-cleared product to aid in weight management, as well as potential therapies in development for type 2 diabetes, Non-alcoholic Fatty Liver Disease (NAFLD)/Non-alcoholic Steatohepatitis (NASH), and Functional Constipation.

For more information, visit [gelesis.com](https://www.gelesis.com), or connect with us on Twitter @GelesisInc.

### **About the Gelesis Loss of Weight (GLOW) Clinical Study**

The Gelesis Loss of Weight (GLOW) Study was a randomized, 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 reduced calorie 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 events 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 FDA-cleared to aid in weight management in adults with excess weight or obesity, Body Mass Index (BMI) of 25 to 40 kg/m<sup>2</sup>, when used in conjunction with diet and exercise. Plenity is designed to help you feel full while eating less.

The capsules are taken 20-30 minutes before lunch and dinner with 16 oz of water, acting locally in the GI tract to make you feel fuller. Using a novel biomimetic approach, its structure and properties were inspired by vegetables. Plenity is available now in a limited release, with broad commercial availability later in 2021.

### **Important Safety Information**

- Patients who are pregnant or are allergic to cellulose, citric acid, sodium stearyl fumarate, gelatin, or titanium dioxide should not take Plenity.
- To avoid impact on the absorption of medications:
  - For all medications that should be taken with food, take them after starting a meal.
  - For all medications that should be taken without food (on an empty stomach), continue taking on an empty stomach or as recommended by your physician.
- The overall incidence of side effects with Plenity was no different than placebo. The most common side effects were diarrhea, distended abdomen, infrequent bowel movements, and flatulence.
- Contact a doctor right away if problems occur. If you have a severe allergic reaction, severe stomach pain, or severe diarrhea, stop using Plenity until you can speak to your doctor.

**Rx Only.** For the safe and proper use of Plenity or more information, talk to a healthcare professional, read the [Patient Instructions for Use](#), or call 1-844-PLENITY.

For more information, visit [myplenity.com](http://myplenity.com).

### **About PureTech Health**

PureTech is a clinical-stage biotherapeutics company dedicated to discovering, developing and commercializing highly differentiated medicines for devastating diseases, including inflammatory, fibrotic and immunological conditions, intractable cancers, lymphatic and gastrointestinal diseases and neurological and neuropsychological disorders, 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 26 therapeutics and therapeutic candidates, including two that have received FDA clearance and European marketing authorization, as of the date of PureTech's most recently filed Annual Report on Form 20-F. All of the underlying programs and platforms that resulted in this pipeline of therapeutic 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.

### **Cautionary Note Regarding Forward-Looking Statements**

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,

expectations regarding the benefits expected from Plenity based on the analysis presented at AACE, expectations regarding Gelesis' plans to enroll the first patient in a clinical study of its OSH GS300 therapeutic candidate, including the timing thereof, and 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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