

# PureTech Founded Entity Gelesis Announces Clinical Data Demonstrating Weight Loss with GS200 in Adults with Prediabetes and Type 2 Diabetes Presented at the European Congress on Obesity 2022

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## **PureTech Founded Entity Gelesis Announces Clinical Data Demonstrating Weight Loss with GS200 in Adults with Prediabetes and Type 2 Diabetes Presented at the European Congress on Obesity 2022**

*Gelesis' six-month study of weight loss in adults with overweight or obesity who have prediabetes or type 2 diabetes met both of its primary endpoints: the proportion of participants who achieved at least 5% body weight loss (i.e., "Categorical") and the change in body weight after six months of therapy*

*GS200 demonstrated a highly favorable Categorical weight loss response and tolerability in a population that often struggles to lose weight and is at high risk for obesity-related complications; the overall incidence of adverse events (AEs) in adults treated with GS200 was similar to the placebo group*

*~6 out of 10 GS200-treated adults achieved at least 5% weight loss ("Responders"), losing on average 11% (~23 pounds), or 5.5 inches off their waist circumference in only 24 weeks*

*~1 out of 3 GS200-treated adults were "super responders," losing at least 10% of their body weight and on average losing 13% (~30 pounds), or 7 inches off their waist circumference in only 24 weeks*

[PureTech Health plc](#) (Nasdaq: PRTC, LSE: PRTC) ("PureTech" or the "Company"), a clinical-stage biotherapeutics company announced that its Founded Entity, Gelesis Holdings, Inc. (NYSE: GLS) ("Gelesis"), a consumer-focused biotherapeutics company and the maker of Plenity®, today presented results from the LIGHT-UP clinical trial for adults with overweight or obesity who have prediabetes or type 2 diabetes and were treated with either GS200 or placebo. Approximately 6 out of 10 adults treated with GS200 achieved clinically meaningful response to treatment (achieving at least 5% body weight loss), losing on average 11% of their body weight (~23 pounds) and an average reduction of 5.5 inches off their waist circumference. Approximately 1 out of 3 GS200-treated adults were "super responders," losing at least 10% of their body weight and on average losing 13% (~30 pounds), or 7 inches off their waist circumference. The overall incidence of adverse events (AEs) in adults treated with GS200 was similar to the incidence of AEs in the placebo group. The detailed findings were presented at three poster presentations at the European Congress on Obesity 2022.

GS200 is an orally administered superabsorbent hydrogel taken by capsule with water 10 minutes before lunch and dinner and is designed to act mechanically in the gastrointestinal tract in order to induce satiety in patients with

prediabetes and type 2 diabetes. Participants in LIGHT-UP were also instructed to follow a modestly reduced calorie diet along with moderate-intensity physical activity. In the GS200 group there was clear and early separation between responders and non-responders to treatment, and response to therapy could be predicted as early as 6 weeks of treatment.

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

*Clinical Data Presented at the European Congress on Obesity 2022 Demonstrates Weight Loss with GS200 in Adults with Prediabetes and Type 2 Diabetes*

*Gelesis' six-month study of weight loss in adults with overweight or obesity who have prediabetes or type 2 diabetes met both of its primary endpoints: the proportion of participants who achieved at least 5% body weight loss (i.e., "Categorical") and the change in body weight after six months of therapy*

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**BOSTON, MAY 4, 2022** - Gelesis (NYSE: GLS), a consumer-focused biotherapeutics company and the maker of Plenity®, today presented results from the LIGHT-UP clinical trial for adults with overweight or obesity who have prediabetes or type 2 diabetes and were treated with either GS200 or placebo. Approximately 6 out of 10 adults treated with GS200 achieved clinically meaningful response to treatment (achieving at least 5% body weight loss), losing on average 11% of their body weight (~23 pounds) and an average reduction of 5.5 inches off their waist circumference. Approximately 1 out of 3 GS200-treated adults were "super responders," losing at least 10% of their body weight and on average losing 13% (~30 pounds), or 7 inches off their waist circumference. The overall incidence of adverse events (AEs) in adults treated with GS200 was similar to the incidence of AEs in the placebo group. The detailed findings were presented at three poster presentations at the European Congress on Obesity 2022.

Anti-obesity medications are prescribed in less than 2% of people with overweight or obesity in the US mainly due to concerns about the safety or tolerability of existing medications. There is a need for orally administered treatments that can induce clinically meaningful weight loss, with no significant increased safety risk, especially in people with type 2 diabetes or prediabetes since they typically face increased challenges losing weight and have higher risk of developing serious comorbidities.

"There is a very large population of adults with prediabetes and diabetes who have a greater need for weight loss due to higher medical risks and a greater difficulty losing weight," said Frank L. Greenway, MD, Medical Director and Professor at the Pennington Biomedical Research Center of the Louisiana State University and one of the study's lead investigators. "The compelling weight loss data that favors diabetes and prediabetes is unique among weight loss treatments. Its convenient oral administration, and very favorable tolerability make it a potentially important tool to aid clinicians and patients achieve clinically meaningful weight loss."

GS200 is an orally administered superabsorbent hydrogel taken by capsule with water 10 minutes before lunch and dinner and is designed to act mechanically in the gastrointestinal tract in order to induce satiety in patients with prediabetes and type 2 diabetes. Participants in LIGHT-UP were also instructed to follow a modestly reduced calorie diet along with moderate-intensity physical activity. In the GS200 group there was clear and early separation between responders and non-responders to treatment, and response to therapy could be predicted as early as 6 weeks of treatment.

"There is a real need for tolerable, effective, and affordable therapeutics to aid in weight loss for patients with prediabetes and type 2 diabetes. Approximately 130 million Americans have prediabetes or type 2 diabetes and approximately 80% struggle with excess weight. Importantly, these individuals also have a high risk of heart disease and other serious chronic conditions, related to overweight and obesity, making this one of the biggest public health issues facing our society," said Harry L. Leider, MD, MBA, FACPE, Chief Medical Officer of Gelesis. "These data show that GS200 produces clinically meaningful weight loss for the majority of patients and that it's possible to identify these responders early in treatment. Given the highly attractive safety and tolerability profile, GS200 has the potential to become an exciting new therapy, especially among those in the lower spectrum of excess weight who also have prediabetes or type 2 diabetes."

## About Gelesis' LIGHT-UP Clinical Study

The multicenter, double-blind, randomized, placebo-controlled study enrolled 254 subjects and was designed to assess the change in body weight in adults with overweight or obesity, who have prediabetes or diabetes, after six months of treatment with a new oral superabsorbent hydrogel (GS200) or placebo. The study met both of its primary endpoints: the proportion of participants who achieved at least 5% body weight loss and the change in body weight after six months of therapy.

A highly binary effect was observed with the GS200 treatment group, with a clear separation between responders and non-responders as early as after 6 weeks of treatment. Among the adults who completed the study protocol requirements (PP population), 64% of GS200-treated adults were Responders vs. 41% in the placebo group ( $p=0.001$ ). In the analysis which also included data from the participants who didn't fully complete the study (ITT-MI), 55% of GS200-treated adults were Responders vs. 34% in the placebo group ( $p=0.0004$ ). The average body weight loss of the Responders was 11% (approximately 23 pounds) and their waist circumference was reduced by 5.5 inches on average. Importantly, Gelesis treated individuals had 2.8 higher odds compared with placebo to become Responders (adjusted odds ratio = 2.83,  $P=0.0004$ ), achieving the first primary endpoint of the study.

With respect to average total weight loss, the complete GS200 treatment group (including both Responders and Non-Responders) demonstrated superiority over placebo after 6 months of treatment (body weight loss of 7.1% vs. 4.6%,  $P=0.0029$  in the PP population or 6.9% vs. 4.3%,  $P=0.0011$  in the ITT population), thereby achieving the second primary endpoint.

GS200 demonstrated a highly favorable safety and tolerability profile as the overall incidence of adverse events (AEs) in adults treated with GSP200 was similar to the incidence of AEs in the placebo group.

## About GS200

GS200 is a non-systemic, superabsorbent hydrogel in development for the treatment of obesity and for glycemic control. It is made by utilizing the same proprietary hydrogel platform technology Gelesis developed for its previously FDA cleared product, GS100 (Plenity™). Like GS100, GS200 is made from naturally derived cross-linked modified cellulose, however with a higher molecular weight. GS200 was designed to hydrate faster and create a higher elastic response in the GI tract compared with GS100. Its properties were optimized in preclinical studies based on its effect on the gut barrier and microbiome, as well as reduced insulin resistance and weight loss. Like GS100, GS200 is a three-dimensional matrix of cellulose, capable of absorbing a much larger volume of water in the stomach and small intestines. Orally administered in capsules with water before meals, GS200 particles rapidly absorb water in the stomach and homogeneously mix with ingested food. This creates thousands of small individual gel pieces with composition (cellulose and water) and elasticity (firmness) similar to solid ingested raw vegetables, without any caloric value. Once it arrives in the large intestine, the hydrogel is partially broken down by naturally occurring 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 expelled naturally. GS200 is considered a medical device because it achieves its primary intended purpose through mechanical modes of action consistent with mechanobiology constructs, and it is not absorbed through the gastrointestinal tract. GS200 received a Non-Significant Risk (NSR) determination by the FDA for the LIGHT-UP study.

## About Gelesis

Gelesis Holdings Inc. (NYSE: GLS) ("Gelesis") is a consumer-centered biotherapeutics company and the maker of Plenity®, which is inspired by nature and FDA cleared to aid in weight management. Our first-of-its-kind non-systemic superabsorbent hydrogels are made entirely from naturally derived building blocks. They are inspired by the composition and mechanical properties of raw vegetables, taken by capsule, and act locally in the digestive system, so people feel satisfied with smaller portions. Our portfolio includes commercially available Plenity® and potential therapies in development for patients with 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.

Plenity® is indicated to aid weight management in adults with excess weight or obesity, a Body Mass Index (BMI) of 25-40 kg/m<sup>2</sup>, when used in conjunction with diet and exercise.

## Important Safety Information about Plenity

- 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.

### **Forward-Looking Statements**

Certain statements, estimates, targets and projections in this press release may constitute "forward-looking statements" within the meaning of the federal securities laws. The words "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "might," "plan," "possible," "potential," "predict," "project," "should," "strive," "would" and similar expressions may identify forward-looking statements, but the absence of these words does not mean that statement is not forward looking. Forward-looking statements are predictions, projections and other statements about future events that are based on current expectations and assumptions and, as a result, are subject to risks and uncertainties. Forward-looking statements include, but are not limited to, statements regarding our or our management team's expectations, hopes, beliefs, intentions or strategies regarding the future, including those relating to Gelesis' business combination with Capstar Special Purpose Acquisition Corp. ("Capstar") and its expected benefits, Gelesis' performance following the business combination, the competitive environment in which Gelesis operates, the expected future operating and financial performance and market opportunities of Gelesis and statements regarding Gelesis' expectations, hopes, beliefs, intentions or strategies regarding the future. In addition, any statements that refer to projections, forecasts, or other characterizations of future events or circumstances, including any underlying assumptions, are forward-looking statements. Forward-looking statements speak only as of the date they are made. Readers are cautioned not to put undue reliance on forward-looking statements, and Gelesis assumes no obligation and does not intend to update or revise these forward-looking statements, whether as a result of new information, future events, or otherwise. Gelesis gives no assurance that any expectations set forth in this press release will be achieved. Various risks and uncertainties (some of which are beyond our control) or other factors could cause actual future results, performance or events to differ materially from those described herein. Some of the factors that may impact future results and performance may include, without limitation: (i) the size, demand and growth potential of the markets for Plenity® and Gelesis' other product candidates and Gelesis' ability to serve those markets; (ii) the degree of market acceptance and adoption of Gelesis' products; (iii) Gelesis' ability to develop innovative products and compete with other companies engaged in the weight loss industry; (iv) Gelesis' ability to finance and complete successfully the commercial launch of Plenity® and its growth plans, including new possible indications and the clinical data from ongoing and future studies about liver and other diseases; (v) failure to realize the anticipated benefits of the business combination, including as a result of a delay or difficulty in integrating the businesses of Capstar and Gelesis; (vi) the ability of Gelesis to issue equity or equity-linked securities or obtain debt financing in the future; (vii) the outcome of any legal proceedings instituted against Capstar, Gelesis, or others in connection with the business combination; (viii) the ability of Gelesis to maintain its listing on the New York Stock Exchange; (ix) the risk that the business combination disrupts current plans and operations of Gelesis as a result of Gelesis being a publicly listed issuer; (x) the regulatory pathway for Gelesis' products and responses from regulators, including the FDA and similar regulators outside of the United States; (xi) the ability of Gelesis to grow and manage growth profitably, maintain relationships with customers and suppliers and retain Gelesis' management and key employees; (xii) costs related to the business combination, including costs associated with the Gelesis being a publicly listed issuer; (xiii) changes in applicable laws or regulations; (xiv) the possibility that Gelesis may be adversely affected by other economic, business, regulatory and/or competitive factors; (xv) Gelesis' estimates of expenses and profitability; (xvi) ongoing regulatory requirements, (xvii) any competing products or technologies that may emerge, (xviii) the volatility of the telehealth market in general, or insufficient patient demand; (xix) the ability of Gelesis to defend its intellectual property and satisfy regulatory requirements; (xx) the impact of the COVID 19 pandemic on Gelesis' business; (xxi) the limited operating history of Gelesis; (xxii) the potential impact of inflation on our operating expenses and costs of goods; and (xxiii) other important factors discussed in the "Risk Factors" section of Gelesis's most recent Annual Report on Form 10-K filed on April 1, 2022, and in other filings that Gelesis makes with the Securities and Exchange Commission. These filings address other important risks and uncertainties that could cause actual results and events to differ

materially from those contained in the forward-looking statements.

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### **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 27 therapeutics and therapeutic candidates, including two that have received both U.S. FDA clearance and European marketing authorization, as of the date of PureTech's most recently filed Annual Report and corresponding Form 6-K. 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 unique insights in immunology and drug development.

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 within the meaning of the Private Securities Litigation Reform Act of 1995. All statements contained in this press release that do not relate to matters of historical fact should be considered forward-looking statements, including without limitation statements that relate to the business combination agreement between Gelesis and Capstar Special Purpose Acquisition Corp. (NYSE: CPSR) or matters related thereto, the potential of GS200 to become a foundational therapy, and Gelesis' future prospects, development plans, and strategies. The forward-looking statements are based on current expectations and are subject to known and unknown risks, uncertainties and other important factors that could cause actual results, performance and achievements to differ materially from current expectations, including, but not limited to, those risks, uncertainties and other important factors described under the caption "Risk Factors" in our Annual Report on Form 20-F for the year ended December 31, 2021 filed with the SEC and in our other regulatory filings. 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, we disclaim any obligation to update or revise these forward-looking statements, whether as a result of new information, future events or otherwise.

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