PureTech Health Affiliate Gelesis Announces Successful FDA Milestone for First Product, PLENITY™

April 14, 2019

FDA Clearance of PLENITY™ is a landmark milestone for PureTech Health, which helped conceive and develop the platform

PLENITY is FDA cleared for the largest number of adults struggling with overweight and obesity (BMI 25-40 kg/m^2) of any prescription weight-management aid and the first that can be used, along with diet and exercise, in millions of overweight adults who have never before had prescription options

~6 out of 10 adults treated with PLENITY were responders, losing on average 10% of their weight (22 pounds) and 3.5 inches from their waists within 6 months in pivotal study

PLENITY is a new 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

Webcast and conference call tomorrow (15 April) at 12:00PM BST / 7:00AM EDT

PureTech Health plc (LSE: PRTC) ("PureTech Health"), an advanced biopharmaceutical company developing novel medicines for dysfunctions of the Brain-Immune-Gut (BIG) axis, today announced that its affiliate, Gelesis, has received marketing clearance from the United States Food and Drug Administration (FDA) for its first product, PLENITY™(Gelesis100), a new and differentiated aid in weight management in adults with a Body Mass Index (BMI) of 25-40 kg/m^2, when used in conjunction with diet and exercise. Nearly 150 million adults in the United States fall into this wide BMI range. PLENITY is the only prescription weight management product to be cleared for use by overweight adults with a BMI as low as 25 kg/m^2, with or without comorbidities such as hypertension, type 2 diabetes or dyslipidaemia.

PLENITY is an orally administered capsule containing a non-stimulant, non-systemic, superabsorbent hydrogel. It is designed to absorb water and increase the volume and elasticity of the stomach and small intestine contents to help people feel full. Gelesis plans to initiate a targeted U.S. launch of PLENITY in the second half of 2019 and anticipates PLENITY will be broadly available by prescription in the U.S. in 2020.

Eric Elenko, PhD, co-founder and chief innovation officer at PureTech Health, said: "This FDA clearance of PLENITY ™ marks a major accomplishment for PureTech Health and Gelesis. We congratulate the Gelesis team for bringing a truly novel approach for weight management to a vast population of people who have had limited or no prescription treatment options until now. The experienced commercial team at Gelesis is well-positioned to launch this exciting new therapy along with a deep base of investors who will help to support the launch.

"In-line with PureTech's overarching scientific focus and leadership in the BIG axis, Gelesis is developing its novel hydrogel platform technology for other chronic diseases such as non-alcoholic steatohepatitis and inflammatory bowel disease through its proprietary approach focused on modulating the gastrointestinal pathway.

"Committed to developing innovative medicines to address some of the largest health issues facing society today, PureTech Health has developed seven novel platforms from concept to clinical validation across our affiliate pipeline. FDA clearance of PLENITY is a landmark moment, providing strong validation of PureTech's ability to identify and develop an emerging area of biology into a new category of medicine for diseases with significant patient need. We look forward to building on this significant milestone with the many upcoming catalysts across our internal and affiliate pipelines."

Webcast and conference call tomorrow at 12:00PM BST, 7:00AM EDT

Members of the Gelesis and PureTech Health senior management teams will host a conference call at 12:00PM BST / 7:00AM EDT tomorrow, 15 April, to discuss this announcement. A live webcast of the conference call and presentation slides will be available on the investors section of PureTech's website (http://puretechhealth.com/investors) under the Reports and Presentations tab. To join the conference call please dial:

UK Toll Free Number: 0800 368 2276

US Toll Free Number: 1 866 966 5335

Standard International Access: +44 (0) 20 3037 9315

Participants should log on approximately 10 minutes in advance to download slides and ensure proper setup to receive the webcast. For those unable to listen to the call live, a replay will be available on the PureTech Health website following the call.

The full text announcement from Gelesis is as follows:

Gelesis Granted FDA Clearance to Market PLENITY™—a New Prescription Aid in Weight Management

PLENITY is FDA cleared for the largest number of adults struggling with overweight and obesity (BMI 25-40 kg/m^2) of any prescription weight-management aid and the first that can be used, along with diet and exercise, in millions of overweight adults who have never before had prescription options

~6 out of 10 adults treated with PLENITY were responders, losing on average 10% of their weight (22 pounds) and 3.5 inches from their waists within 6 months in pivotal study

PLENITY is a new 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

BOSTON, April 14, 2019 —Gelesis, a biotechnology company developing first-in-class hydrogel therapeutics to treat obesity and other chronic diseases related to the gastrointestinal (GI) tract, today announced that the United States Food and Drug Administration (FDA) has cleared the Company's lead product candidate, PLENITY™ (Gelesis100), as an aid in weight management in adults with a Body Mass Index (BMI) of 25–40 kg/m^2, when used in conjunction with diet and exercise. A BMI of 25 kg/m^2 and over is the accepted definition of overweight, and a BMI of 30 kg/m^2 and above commonly defines obesity.

PLENITY represents a new prescription option for millions of adults. More than half of the approximately 150 million adults in the U.S. with a BMI ranging from 25 kg/m^2 to 40 kg/m^2 are classified as overweight (BMI 25-30 kg/m^2). Until now, many of them have not had any prescription treatment options. The safety and efficacy profile of PLENITY makes it well-suited for these individuals. It is the only prescription weight management product to be cleared for use by overweight adults with a BMI as low as 25 kg/m^2, with and also without comorbidities such as hypertension, type 2 diabetes or dyslipidemia. There is no restriction on how long PLENITY can be used to assist in weight management.

"This FDA clearance is a major milestone for the Gelesis team and our technology, and we are thrilled to be able to bring this new prescription product to the millions of people looking for a safe, validated and convenient treatment option to manage their weight without surgery or stimulants," said Yishai Zohar, founder and chief executive officer of Gelesis. "With PLENITY, Gelesis is introducing a completely new approach with a unique mechanism of action to aid in weight management, with efficacy and safety supported by positive data from large clinical studies."

PLENITY is administered in the form of capsules taken with water before lunch and dinner. PLENITY is made by cross-linking two naturally-derived building blocks – cellulose and citric acid – to create a three-dimensional hydrogel matrix. The capsules release thousands of non-aggregating particles that rapidly absorb water in the stomach, creating small individual gel pieces with the elasticity (firmness) of plant-based foods (e.g., vegetables) without caloric value. The gel pieces increase the volume and elasticity of the stomach and small intestine contents, contributing to a feeling of fullness and inducing weight loss. This novel, non-stimulant and non-systemic treatment has been shown in clinical studies to be effective, safe and well-tolerated.

In clinical studies, PLENITY demonstrated a unique combination of effectiveness combined with a highly favourable safety and tolerability profile. Data from the PLENITY pivotal study, Gelesis Loss Of Weight (GLOW), were published recently in the scientific journal *Obesity* and that paper was selected as an Editor's Choice manuscript. Pivotal data from the GLOW study were also presented in three posters, one receiving a special recognition award, and an oral presentation at the Obesity Society Annual Meeting 2018.

"Given the complexity of the disease of obesity and the need for expanded treatment options, the Obesity Action Coalition is encouraged to see continued innovation in safe and effective chronic weight management options. We welcome PLENITY's addition as a treatment option for people affected by obesity," said Joe Nadglowski, president and chief executive officer of the Obesity Action Coalition.

"More than 150 million Americans struggle with excess or unhealthy weight. Unfortunately, the majority of individuals with weight issues have important weight-related medical problems. There is no doubt that making a significant impact on this issue should be America's number one public health priority. The scientific data supporting PLENITY's positive effects on weight make it a powerful tool to help with weight management. The most compelling aspects of this approach are its effectiveness, novel mechanism of action and impressive safety data. This approach creates another arm in the treatment algorithm of weight management and could be used by an overwhelming majority of people struggling with weight issues," said Ken Fujioka, M.D., a weight loss expert, endocrinology researcher at Scripps Clinic and scientific advisor to Gelesis.

Gelesis plans to initiate a targeted U.S. launch of PLENITY in the second half of 2019 and anticipates PLENITY will be broadly available by prescription in the U.S. in 2020.

Clinical studies of PLENITY

PLENITY and its prototypes have been studied across five clinical studies throughout the United States, Canada, and Europe. PLENITY, along with diet and exercise, helps to induce weight loss through increased satiety and reduced hunger, leading to a reduction in caloric intake. Throughout its clinical programme, PLENITY has demonstrated a consistently strong safety and efficacy profile.

PLENITY was recently evaluated in a multicentre, double-blind, placebo-controlled pivotal study designed to assess change in body weight in 436 adults with overweight or obesity (BMI ≥ 27 and ≤ 40 kg/m^2) after six months of treatment. The study had two predefined co-primary endpoints: at least 35% of patients taking PLENITY achieving ≥ 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. As previously announced, 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 than 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 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^2, when used in conjunction with diet and exercise. It 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 homogenously mix with ingested foods. Rather than forming one large mass, it creates thousands of small individual gel pieces with the elasticity

(firmness) of solid plant-based foods (e.g., vegetables) without caloric value. The PLENITY hydrogel mass 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 expelled in the faeces. 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.

Important Safety Information

- PLENITY is contraindicated in patients who are pregnant or are allergic to cellulose, citric acid, sodium stearyl fumarate, gelatin, or titanium oxide
- PLENITY may alter the absorption of medications. Read Sections 6 and 8.3 of the Instructions for Use carefully
- Avoid use in patients with the following conditions: esophageal anatomic anomalies, including webs, diverticuli, and rings; suspected strictures (such as patients with Crohn's disease); or complications from prior gastrointestinal (GI) surgery that could affect GI transit and motility.
- Use with caution in patients with: active GI conditions such as gastro-esophageal reflux disease (GERD), ulcers, or heartburn.
- Overall, the most common treatment related adverse events (TRAEs) were GI-related TRAEs with 38% of adults in the PLENITY group and 28% of adults in the placebo group experiencing a GI-related TRAE.
- The overall incidence of AEs in the PLENITY group was no different than the placebo group

Rx Only. For the safe and proper use of PLENITY, refer to the 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 chronic diseases. In April 2019, Gelesis received FDA clearance for its lead product candidate, PLENITY^{TM}, as an aid for weight management in overweight and obese adults with a Body Mass Index (BMI) of 25-40 kg/m^2, when used in conjunction with diet and exercise. Gelesis is preparing to initiate a targeted U.S. launch of PLENITY in the second half of 2019 and anticipates PLENITY will be broadly available by prescription in the U.S. in 2020. Additionally, Gelesis is developing its second 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 through a pipeline in other GI inflammatory conditions where gut barrier and gut permeability potentially play a role, such as non-alcoholic steatohepatitis (NASH) and inflammatory bowel disease (IBD).

The Gelesis executive and advisory team includes some of the world's leading experts in obesity, materials science, chronic disease research and commercialisation. Gelesis was co-founded by PureTech Health (LSE: PRTC), a biopharmaceutical company focused on the Brain-Immune-Gut (BIG) axis. For more information, visit gelesis.com or connect with us on Twitter @GelesisInc.

About PureTech Health

PureTech Health (LSE: PRTC) is an advanced biopharmaceutical company developing BIG medicines for dysfunctions of the Brain-Immune-Gut axis. The Company has gained deep insights into the connection between these systems and the resulting role in diseases that have proven resistant to established therapeutic approaches. By harnessing this emerging field of human biology, PureTech Health is developing new categories of medicines with the potential to have great impact on people with serious diseases.

PureTech Health is advancing a rich pipeline of innovative therapies with an unbiased, non-binary, and capital efficient R&D model across its affiliates and its internal labs. PureTech's affiliates include seven clinical-stage platforms, including one product that has been cleared by the US Food and Drug Administration (FDA) and a second product candidate that has been filed with the FDA for review, and several other novel preclinical programmes. The PureTech Health pipeline includes ground-breaking platforms and therapeutic candidates that were developed in collaboration with some of the world's leading experts.

PureTech's internal research and development is centred on tissue-selective immunomodulation for the treatment of oncology, autoimmune, and CNS-related disorders, with a near-term focus on targeting newly-discovered, foundational immunosuppressive mechanisms in oncology and novel approaches that harness the lymphatic infrastructure.

For more information, visit 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.

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