PureTech Founded Entity Gelesis Receives Approval to Market PLENITY™ in Europe as a Weight Loss Treatment

June 2, 2020

CE Mark enables Gelesis to market Plenity ™throughout the European Economic Area

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 that it has received approval to market Plenity™, a novel weight loss treatment, in Europe. Gelesis received a Conformité Européenne (CE) mark for Plenity as a class III medical device indicated for weight loss 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 will now be able to market Plenity throughout the European Economic Area and in other countries that recognise the CE mark. Gelesis previously received clearance for Plenity from the US Food and Drug Administration and plans to bring Plenity to the US first, where it is now available to a limited extent while the company ramps up its commercial operations and inventory for a broad launch in 2021.

Eric Elenko, PhD, chief innovation officer at PureTech, said: "This is an important milestone for Gelesis and for the millions of adults across Europe who are seeking to manage their weight. We look forward to continued progress from Gelesis' novel hydrogel platform and to the broad launch of Plenity across of the world."

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

Gelesis Receives Approval to Market PLENITY ™ in Europe as a Weight Loss Treatment

CE Mark enables Gelesis to market Plenity ™throughout the European Economic Area

BOSTON, June 2, 2020 —Gelesis, a biotechnology company developing a novel hydrogel platform technology to treat obesity and other chronic diseases related to the gastrointestinal (GI) tract, announced today that it has received approval to market Plenity™, a novel weight loss treatment, in Europe. Gelesis received a Conformité Européenne (CE) mark for Plenity as a class III medical device indicated for weight loss 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.

"Seventy percent of the western world is affected by overweight or obesity and there are few non-invasive, non-systemic solutions without major risks," says John Wilding, MD, FRCP, a clinical researcher Obesity, Diabetes and Endocrinology at the University of Liverpool and the incoming president of the World Obesity Federation. "Through my participation in the clinical trial, I saw firsthand the impact Plenity can have. The CE mark will further broaden access to a weight loss option that can impact tens of millions of patients globally."

The CE mark indicates that Plenity has been assessed to meet health and safety standards for products sold within the European Economic Area (EEA), as required by the European Medical Device Directives. Gelesis will now be able to market Plenity throughout the EEA and in other countries that recognise the CE mark.

"Obesity is a global public health crisis, and too many individuals have struggled to lose weight on their own, without an effective therapeutic intervention to help them. We believe Plenity is a highly differentiated option for this serious public health issue," said Yishai Zohar, founder and chief executive officer of Gelesis. "Receiving the CE mark is an important milestone for the Gelesis team and for our hydrogel technology platform."

Gelesis plans to bring Plenity to the US first, where it is now available by prescription to a limited extent while the company ramps up its commercial operations and inventory for a broad launch in 2021.

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 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.

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.

- 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 with 38% of adults in the PLENITY group and 28% of adults in the placebo group.
- The overall incidence of adverse events (AEs) in the PLENITY group was no different than the placebo group.

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^2, when used in conjunction with diet and exercise. Plenity is currently available in limited supply 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 Chronic Idiopathic Constipation (CIC). Gelesis was named one of Fast Company's Most Innovative Companies for 2020.

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). For more information, visit 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 23 product candidates and one product that has been cleared by the US Food and Drug Administration (FDA). 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 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.