PureTech Affiliate Akili Announces AKL-T03 Achieved Primary Endpoint, Improving Cognitive Impairments in Major Depressive Disorder Trial

December 13, 2019

Data Presented at the 58th Annual Meeting of the American College of Neuropsychopharmacology

PureTech Health plc (LSE: PRTC) ("PureTech"), a clinical stage biotechnology company dedicated to discovering, developing and commercialising highly-differentiated medicines for devastating diseases, is pleased to note that its affiliate, Akili, today announced the results of its randomised, controlled trial of digital therapeutic AKL-T03 as a treatment for cognitive impairments adjunct to anti-depressant medication in adults with Major Depressive Disorder (MDD). In the study, AKL-T03 demonstrated a statistically significant improvement in sustained attention compared to control. AKL-T03 is designed to improve specific cognitive functions and may play a complementary role to antidepressants in the holistic treatment of MDD. Results of the study were presented yesterday at the 58th Annual Meeting of the American College of Neuropsychopharmacology.

Eric Elenko, PhD, chief innovation officer at PureTech, said: "We are pleased with these results as they provide additional support for the potential of Akili's proprietary digital treatment platform across multiple indications."

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

Akili Technology Improves Cognitive Impairments in Adults with Major Depressive Disorder

Primary Endpoint Achieved in Randomised, Controlled Trial of Digital Therapeutic AKL-T03 in Major Depressive Disorder (MDD)

Data Presented at the 58th Annual Meeting of the American College of Neuropsychopharmacology

BOSTON, December 12, 2019 – Akili Interactive ("Akili" or "Company"), today announced results of its randomised, controlled study of digital therapeutic AKL-T03 as a treatment for cognitive impairments adjunct to anti-depressant medication in adults with MDD. AKL-T03 demonstrated a statistically significant improvement in sustained attention compared to control. Results of the study were presented yesterday at the 58th Annual Meeting of the American College of Neuropsychopharmacology (ACNP).

Cognitive impairment is a fundamental diagnostic criterion of depression, and the majority of people living with MDD experience substantial cognitive issues, including with attention, decision-making and processing speed. Such cognitive impairments have been shown to be a predictor of daily function. More than 16 million people are living with MDD, and a majority have cognitive deficits on neuropsychological tests and/or self-report cognitive issues, yet their options for treatment are limited.

"The majority of patients with MDD experience cognitive impairments, significantly impacting their day-to-day function and quality of life as well as in their risk of recurrence of depression. These impairments are as important to treat as the classical depressive symptoms and, for many patients, persist even after successful antidepressant treatment," said Richard Keefe, PhD, Professor of Psychiatry at Duke University Medical Center and primary investigator of the study. "Based on the results of this study, when combined with antidepressants, AKL-T03 potentially represents a low-risk treatment option that appears to improve cognitive impairments in MDD where few options are available for patients today."

AKL-T03 is designed to improve specific cognitive functions and may play a complementary role to antidepressants in the holistic treatment of MDD. AKL-T03 was built on Akili's SSME technology engine, which deploys sensory and motor stimuli to target and activate the fronto-parietal network in the brain, known to play a key role in cognitive function. The treatment is delivered through a captivating action video game to drive enjoyment and compliance.

"We believe cognitive issues represent one of the major unmet medical needs of the next decade and have a debilitating effect on the lives of millions of people, both with and without medical diagnoses," said Eddie Martucci, CEO of Akili Interactive. "We're very encouraged by the results of our study of AKL-T03, which add to our growing body of data on our SSME technology engine's ability to improve cognitive impairments across a number of populations in need."

In the study, AKL-T03 showed a statistically significant improvement in sustained attention compared to control (p=0.002) on the predefined primary endpoint, as measured by the Test of Variables of Attention (T.O.V.A.®), an FDA-cleared objective measure of attention. Engagement with AKL-T03 also showed a strong correlation with improved processing speed. AKL-T03 was shown to be safe in this study, with no serious adverse events observed. Results of the study will be submitted for publication in a peer-reviewed journal.

For Patients

In this study, the potential digital treatment, AKL-T03, was compared to a non-therapeutic product (the control) to evaluate AKL-T03's safety and ability to improve certain cognitive impairments and, specifically, sustained attention, which is ability to focus on an activity over a long period of time. The study showed that AKL-T03 significantly improved patients' sustained attention as compared to the control which did not show an improvement. Engagement with AKL-T03 was also shown to be associated with improved processing speed, or the time required to complete a specific task. At this time, AKL-T03 is not yet available for patient use outside of clinical studies. For more information on Akili's clinical studies, please visit www.clinicaltrials.org and talk with your doctor.

Study Design

The study was a multi-centre, randomised, controlled trial of AKL-T03 in over 80 adult participants diagnosed with mild-to-moderate MDD symptoms and with mild-to-moderate cognitive impairment. All participants were on stable antidepressant medication. Participants were randomised 1:1 to

AKL-T03 (video game-based digital therapeutic) or a control (video game designed with similar reward and engagement of AKL-T03). Both groups used the treatment/control at home, 5 days per week for 25 minutes per day, on a tablet device for six weeks. Following the treatment period, an in-clinic assessment was conducted to assess key outcomes. The primary outcome of the study assessed sustained attention as measured by Test of Variables of Attention (T.O.V.A.®). The study was managed by VeraSci.

About Akili

Akili is combining scientific and clinical rigor with the ingenuity of the tech and entertainment industries to challenge the status quo of medicine. Akili is pioneering the development of digital treatments and care solutions to help people affected by cognitive impairments. Akili's treatments directly activate the networks in the brain responsible for cognitive function and have been rigorously tested in extensive clinical studies, including prospective randomised, controlled trials. Driven by Akili's belief that effective medicine can also be fun and engaging, Akili's treatments are delivered through captivating action video game experiences. For more information, please visit www.akiliinteractive.com.

About PureTech Health

PureTech is a clinical stage biotechnology 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 affiliates, is comprised of 24 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.