PureTech Affiliate Akili Announces New AKL-T01 Study Achieved Primary Endpoint in Children with ADHD

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AKL-T01 showed statistically significant improvement in ADHD Impairment Rating Scale (IRS), when used alone and as adjunct to stimulants

Akili continues to pursue FDA clearance for AKL-T01 as a potential treatment of inattention in paediatric ADHD

PureTech Health plc (LSE: PRTC) ("PureTech") is pleased to note that its affiliate, Akili, today announced top-line results of its multi-site open-label study (STARS-ADHD Adjunctive) to evaluate the effects of AKL-T01 in children with Attention Deficit Hyperactivity Disorder (ADHD) when used with and without stimulant medication. The effects of increasing the duration of treatment were also studied. The study achieved its predefined primary efficacy outcome, demonstrating a statistically significant improvement in the ADHD Impairment Rating Scale (IRS) from baseline after one month of treatment ($p<0.001$) in both children taking stimulant medications and in those not taking stimulants.

Eric Elenko, PhD, chief innovation officer at PureTech, said: "We are pleased with these new results as they provide additional support for AKL-T01 in paediatric ADHD – both as a monotherapy and in combination with stimulant medications. This study also builds on the previously reported cognition findings by demonstrating efficacy on the IRS, which is a scale of ADHD-specific symptoms that provides measures of the real-world consequences of ADHD symptoms."

The STARS-ADHD Adjunctive study is the fifth clinical study evaluating AKL-T01 in children with ADHD. In STARS-ADHD, AKL-T01 demonstrated a statistically significant improvement compared to control ($p=0.006$) on the predefined primary endpoint, a composite score from the Test of Variables of Attention (TOVA®), an objective measure of attention, after one month of treatment. Across all studies to-date, AKL-T01 has been shown to be safe and well tolerated. Akili filed for clearance of AKL-T01 for the treatment of children with ADHD with the United States Food and Drug Administration (FDA) in 2018. Clearance has not yet been granted, and Akili continues to work with FDA in an effort to make the product available for children living with ADHD as soon as possible.

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

Akili Study of AKL-T01 With and Without Stimulant Medication in Children with ADHD Achieves Primary Efficacy Endpoint

AKL-T01 showed statistically significant improvement in ADHD Impairment Rating Scale (IRS), when used alone and as adjunct to stimulants

Parents and clinicians saw increased improvements with a longer duration of AKL-T01 treatment

Akili continues to pursue FDA clearance for AKL-T01 as a potential treatment of inattention in paediatric ADHD

BOSTON, Mass – January 15, 2020 – Akili Interactive ("Akili" or "Company"), today announced top-line results of its multi-site open-label study (STARS-ADHD Adjunctive) to evaluate the effects of AKL-T01 in children with Attention Deficit Hyperactivity Disorder (ADHD) when used with and without stimulant medication. The effects of increasing the duration of treatment were also studied. The study achieved its predefined primary efficacy outcome, demonstrating a statistically significant improvement in the ADHD Impairment Rating Scale (IRS) from baseline after one month of treatment ($p<0.001$) in both children taking stimulant medications and in those not taking stimulants.

STARS-ADHD Adjunctive is the first study to look at the efficacy of AKL-T01 when used in combination with stimulant medications and the first to evaluate AKL-T01 over a longer duration of treatment. In the study, similar improvements were seen both in children taking stimulant medications and in those not taking stimulants, suggesting that the effect of AKL-T01 was independent of whether the children were on or off ADHD medication. Additionally, improvements increased after a second month of treatment, with both parents and clinicians noticing additional improvement in these children with a longer duration of treatment. AKL-T01 showed a similar safety profile in this study as has been seen previously, with no serious adverse events observed. Full analysis of the data is underway, and results of the study will be presented at upcoming scientific conferences and submitted for publication in peer-reviewed journals.

"Following our successful pivotal STARS-ADHD study of AKL-T01 as a potential treatment for inattention in children with ADHD not taking stimulant medications, understanding the benefit of our technology when used alongside ADHD medications has been a research priority for us. Importantly, parents see improvements in their children regardless of whether they are using the treatment alone or alongside stimulants," said Eddie Martucci, CEO of Akili. "As we continue to work toward FDA clearance for this novel therapeutic for inattention in children with ADHD, these data and the benefits expressed by parents and physicians in this study lend further credence to the important role AKL-T01 can play in the treatment of ADHD."

More than 5.5 million children diagnosed with ADHD struggle with attention issues. Inattention and other "silent" cognitive issues often go unrecognised in the face of other more overt disease symptoms, yet they significantly impact daily functioning. "Children with ADHD are joined by millions of others, both with and without medical diagnoses, who experience challenges in their daily lives due to inattention or other cognitive issues. We're committed to driving greater awareness and recognition of the impact of these cognitive issues and advancing novel approaches to help all those affected," said Anil Jina, MD, Akili's Chief Medical Officer.

The three-month study enrolled 206 children, aged 8-14 years with a diagnosis of ADHD. The children were separated into two groups: one with children on stimulant medications and one with children not taking ADHD medication. Both groups received a first period of AKL-T01 treatment in the first month of the study, followed by a pause in AKL-T01 treatment in the second month, and then a second period of AKL-T01 treatment in the third

month. The primary efficacy outcome of the study was change in IRS, a parent-reported clinician-administered ADHD impairment scale, after one month of treatment. The study demonstrated statistically significant improvement in the IRS from baseline after one month as well as to the end of the three-month trial in both the children on-stimulants and off-stimulants (both cohorts: $p<0.001$). The second period of AKL-T01 treatment resulted in further increases in efficacy on this primary outcome measure, beyond the effects already seen after the first period of treatment. The magnitude of improvement in IRS throughout the study was similar for children independent of their ADHD medication use. Responder rates for IRS (improvement of greater than 1 point or more on the IRS scale) were 41% and 55% at the end of the first period of treatment with AKL-T01 in the off-stimulant and on-stimulant groups respectively. This increased to 69% and 68% respectively by the end of the second period of treatment. The treatment was safe and well-tolerated. There were no serious adverse events and the most common treatment-related adverse event reported was frustration.

The STARS-ADHD Adjunctive study is the fifth clinical study evaluating AKL-T01 in children with ADHD. In December 2017, Akili announced the results of a prospective, randomised, controlled, one-month trial of AKL-T01 in 348 children with ADHD (STARS-ADHD) who were not taking ADHD medications. In STARS-ADHD, AKL-T01 demonstrated a statistically significant improvement compared to control ($p=0.006$) on the predefined primary endpoint, a composite score from the Test of Variables of Attention (TOVA®), an objective measure of attention, after one month of treatment. IRS was also measured in the STARS-ADHD study; responder rates in the STARS-ADHD study were similar to after one month of AKL-T01 treatment in the STARS-ADHD Adjunctive study and were statistically greater than control. Across all studies to-date, AKL-T01 has been shown to be safe and well tolerated. Akili filed for clearance of AKL-T01 for the treatment of children with ADHD with the United States Food and Drug Administration (FDA) in 2018. Clearance has not yet been granted, and Akili continues to work with FDA in an effort to make the product available for children living with ADHD as soon as possible.

ADHD Impairment Rating Scale (IRS)

The Impairment Rating Scale (IRS) is a parent-reported clinician-administered scale of ADHD-specific impairment across domains such as social functioning, academic progress and self-esteem, including an overall impairment. The domains of ADHD-specific impairment assessed by the IRS correspond to DSM criteria of impaired functioning in social or academic areas for ADHD. The assessment provides measures of real-world consequences of ADHD symptoms.

About AKL-T01 and the STARS-ADHD Adjunctive Study [NCT03649074]

AKL-T01 is a digital therapeutic being evaluated as a potential treatment for inattention in children living with ADHD. AKL-T01 is built on Akili's Selective Stimulus Management engine (SSME™) core technology, which presents a range of specific stimuli designed to target and activate the fronto-parietal network in the brain, known to play a key role in cognitive function and attention. The treatment is delivered through a captivating action video game to help drive engagement and compliance.

SSME has been shown to improve measures of attention in a dozen different indications and has been studied in more than 30 clinical trials. The STARS-ADHD Adjunctive study was a three-month open-label, multi-site study of AKL-T01 in 206 paediatric participants aged 8-14 years with a diagnosis of ADHD. AKL-T01 treatment was evaluated across two groups of participants, one group of children who were taking ADHD stimulant medications (n=130) and one group of children who were not taking ADHD medications (n=76) for the duration of the study. The primary outcome measure of the study was the change from baseline in the ADHD Impairment Rating Scale (IRS) for each cohort after one month. Secondary outcome measures included the ADHD Rating Scale (ADHD-RS), Tests of Variables of Attention (TOVA), Clinical Global Impression - Improvement Scale (CGI-I), as well as academic measures. The study was managed by the Duke Clinical Research Institute.

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 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.