



# PureTech Founded Entity Akili Announces Phase 3 Study of Digital Treatment in Children with ADHD Begun by Shionogi in Japan

August 1, 2022

RNS Number : 3510U  
PureTech Health PLC  
01 August 2022

1 August 2022

PureTech Health plc

## **PureTech Founded Entity Akili Announces Phase 3 Study of Digital Treatment in Children with ADHD Begun by Shionogi in Japan**

*Pivotal study follows successful Phase 2 trial, which demonstrated improvements in attention function as compared to both treatment as usual and single task video game groups*

*Pivotal Data Readout expected in 2H2023*

[PureTech Health plc](#) (Nasdaq: PRTC, LSE: PRTC) ("PureTech" or the "Company"), a clinical-stage biotherapeutics company noted that its Founded Entity, Akili Interactive Labs, Inc. ("Akili"), a leading digital medicine company, today announced the start of a pivotal Phase 3 randomized, controlled study of SDT-001 (a version of AKL-T01 localized for Japanese language and culture), a product candidate designed to improve measures of attention in children diagnosed with attention-deficit/hyperactivity disorder ("ADHD"). The study, conducted by Akili's partner, global pharmaceutical company Shionogi & Co., Ltd. ("Shionogi"), is designed to evaluate the safety and efficacy of the product candidate in children ages 6-17 with ADHD as a registration-enabling trial. Clinical trial sites have begun enrolling patients, and results of the study are expected in 2H2023.

This study represents the first pivotal study of Akili's video game-based cognitive treatment outside of the U.S. SDT-001 was developed specifically for use in the Japanese market, adapting Akili's AKL-T01 for Japanese language and culture. The disease agnostic proprietary technology is designed to treat impaired cognitive function, specifically attention control. Delivered through an action video game experience, this innovative technology presents specific sensory stimuli and simultaneous motor challenges designed to target and activate the neural systems that play a key role in attention function while using adaptive algorithms to personalize the treatment experience for each individual patient.

The pivotal study of SDT-001 is being conducted across multiple sites in Japan and is expected to enroll approximately 150 children ages 6-17 years diagnosed with ADHD. The study design was informed by Shionogi's successful Phase 2 study of SDT-001.

Branded and marketed as EndeavorRx® in the U.S., AKL-T01 is cleared for use by the U.S. Food and Drug Administration (FDA) and has received Conformité Européenne (CE) Mark certification in Europe for use in attention and inhibitory control deficits in pediatric ADHD. Please see below for full indication and safety information.

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

### **Shionogi Begins Phase 3 Study in Japan of Akili's Digital Treatment in Children with ADHD**

*Pivotal study follows successful Phase 2 trial, which demonstrated improvements in attention function as compared to both treatment as usual and single task video game groups.*

*Pivotal Data Readout expected in 2H2023*

**BOSTON, Mass. - August 1, 2022** - Akili Interactive ("Akili"), a leading digital medicine company, today announced the start of a pivotal Phase 3 randomized, controlled study of SDT-001 (a version of AKL-T01 localized for Japanese language and culture), a product candidate designed to improve measures of attention in children diagnosed with attention-deficit/hyperactivity disorder ("ADHD"). The study, conducted by Akili's partner, global pharmaceutical company Shionogi & Co., Ltd. ("Shionogi"), is designed to evaluate the safety and efficacy of the product candidate in children ages 6-17 with ADHD as a registration-enabling trial. Clinical trial sites have begun enrolling patients, and results of the study are expected in 2H2023.

"ADHD has a significant impact on children and their families in Asia, and caregivers and health care providers are looking for innovative non-drug treatment options. Following our successful Phase 2 study of SDT-001, we are excited to advance Akili's product candidate through the clinical process to potentially help the millions of children living in Japan with ADHD," said Takeki Uehara, Corporate Officer, Senior Vice President, Drug Development and Regulatory Science Division of Shionogi & Co., Ltd.

"We are thankful to our partners at Shionogi who share our commitment to patients and have initiated this pivotal study ahead of schedule," said Anil S. Jina M.D., Chief Medical Officer of Akili. "This trial is an important step towards our goal to help all eligible children with ADHD across the globe, irrespective of their language, culture, or geographic location."

The pivotal study of SDT-001 is being conducted across multiple sites in Japan and is expected to enroll approximately 150 children ages 6-17 years diagnosed with ADHD. The study design was informed by Shionogi's successful Phase 2 study of SDT-001. It consists of two parts, a comparison part and a repetition part.

- Comparison part: Qualifying participants are randomized to either 1) receive SDT-001 in addition to treatment as usual ("TAU"), consisting of psychoeducation and environmental support, or 2) continue TAU.
- Repetition part: After completing the comparison part, both groups receive SDT-001.

Participants who receive SDT-001 treatment use the digital intervention for approximately 25 minutes per day, seven days per week for a total of six weeks of treatment. Following treatment, participants' attention function is assessed by physicians using the ADHD-RS-IV inattentive subscale, a commonly used scale in evaluating ADHD treatments, and compared to baseline.

This study represents the first pivotal study of Akili's video game-based cognitive treatment outside of the U.S. SDT-001 was developed specifically for use in the Japanese market, adapting Akili's AKL-T01 for Japanese language and culture. The disease agnostic proprietary technology is designed to treat impaired cognitive function, specifically attention control. Delivered through an action video game experience, this innovative technology presents specific sensory stimuli and simultaneous motor challenges designed to target and activate the neural systems that play a key role in attention function while using adaptive algorithms to personalize the treatment experience for each individual patient. AKL-T01 has been evaluated across five clinical studies in more than 600 children diagnosed with ADHD, including a prospective, randomized, controlled study published in The Lancet Digital Health. The technology is also being studied by Akili in multiple other indications with associated chronic and acute cognitive impairments, including autism spectrum disorder ("ASD"), multiple sclerosis, major depressive disorder, COVID-19 brain fog, cancer-related cognitive impairment and postoperative cognitive dysfunction. Branded and marketed as EndeavorRx® in the U.S., AKL-T01 is cleared for use by the U.S. Food and Drug Administration (FDA) and has received Conformité Européenne

(CE) Mark certification in Europe for use in attention and inhibitory control deficits in pediatric ADHD. Please see below for full indication and safety information.

In September 2021, Akili and Shionogi announced the results of a Phase 2 study of SDT-001 in Japan. The study enrolled a total of 261 children ages 6-17 years diagnosed with ADHD and evaluated their attention impairment using the ADHD RS-IV Inattention scale, comparing those who received the Akili treatment to those receiving TAU and those who received a control app (single task video game). The SDT-001 treatment group showed larger improvements across the clinical endpoints compared to both the TAU and the control app groups. In the total population, the improvements seen over the control app did not meet statistical significance, but post hoc analysis applying the propensity score suggested that SDT-001 improvements over TAU were statistically significant. SDT-001 was well-tolerated and there were no serious adverse events. Adverse events reported were consistent with previous clinical studies of the digital treatment. Adverse device reactions were reported in 4 patients (3.7%) treated with SDT-001 and were mild in severity including irritability, somnolence, tinnitus and nausea.

Akili and Shionogi formed a strategic partnership in May 2019 for the commercialization of Akili's AKL-T01 and AKL-T02, as potential treatments of cognitive impairments in children with ADHD and ASD, respectively, in Japan and Taiwan. The partnership leverages each party's distinct expertise to build a novel commercial model and seek to launch the new class of treatment to patients. Under the terms of the agreement, Shionogi has exclusive rights to the clinical development and is responsible for regulatory filings, sales and marketing of the technologies in Japan and Taiwan. Akili is responsible for building and maintaining R&D and commercial platforms designed specifically for digital therapeutics, including all global product development activities, distribution and technical support services. Akili maintains exclusive global rights to develop and commercialize AKL-T01 and AKL-T02 in all territories outside of Japan and Taiwan.

### **EndeavorRx® Indication and Overview**

EndeavorRx is the first prescription video game treatment granted marketing authorization by the FDA. In the U.S., EndeavorRx is indicated to improve attention function as measured by computer-based testing in children ages 8-12 years old with primarily inattentive or combined-type ADHD, who have a demonstrated attention issue. Patients who engage with EndeavorRx demonstrate improvements in a digitally assessed measure Test of Variables of Attention (TOVA®) of sustained and selective attention and may not display benefits in typical behavioral symptoms, such as hyperactivity. EndeavorRx should be considered for use as part of a therapeutic program that may include clinician-directed therapy, medication, and/or educational programs, which further address symptoms of the disorder. EndeavorRx is available by prescription only. It is not intended to be used as a stand-alone therapeutic and is not a substitution for a child's medication. The most common side effect observed in children in EndeavorRx's clinical trial was a feeling of frustration, as the game can be quite challenging at times. No serious adverse events were associated with its use. EndeavorRx is recommended to be used for approximately 25 minutes a day, 5 days a week, over initially at least 4 consecutive weeks, or as recommended by your child's health care provider.

### **About Akili**

Akili is pioneering the development of cognitive treatments through game-changing technologies. Our approach of leveraging technologies designed to directly target the brain establishes a new category of medicine - medicine that is validated through clinical trials like a drug or medical device but experienced like entertainment. Akili's platform is powered by proprietary therapeutic engines designed to target cognitive impairment at its source in the brain, informed by decades of research and validated through rigorous clinical programs. Driven by Akili's belief that effective medicine can also be fun and engaging, Akili's products are delivered through captivating action video game experiences.

### **Additional Information and Where to Find It**

In connection with the proposed business combination transaction between Social Capital Suvretta Holdings Corp. I ("SCS") and Akili, SCS filed a registration statement on Form S-4 (as amended, the "Registration Statement") with the SEC on February 14, 2022, which includes a document that serves as a prospectus and proxy statement of SCS, referred to as a proxy statement/prospectus. The Registration Statement became effective on July 21, 2022. SCS has mailed a definitive proxy statement/prospectus and other relevant documents to its shareholders of record as of July 14, 2022, the record date established for the extraordinary general meeting of SCS shareholders relating to the

proposed transaction. The proxy statement/prospectus has been distributed to SCS's shareholders in connection with SCS's solicitation of proxies for the vote by SCS's shareholders with respect to the proposed transaction. SCS may also file other documents regarding the proposed transaction with the SEC. BEFORE MAKING ANY VOTING DECISION, SHAREHOLDERS OF SCS ARE ADVISED TO READ THE REGISTRATION STATEMENT, THE PROXY STATEMENT/PROSPECTUS AND ALL OTHER RELEVANT DOCUMENTS FILED OR THAT WILL BE FILED WITH THE SEC IN CONNECTION WITH THE PROPOSED TRANSACTION AS THEY BECOME AVAILABLE BECAUSE THEY WILL CONTAIN IMPORTANT INFORMATION. Shareholders will be able to obtain free copies of the Registration Statement, the proxy statement/prospectus and all other relevant documents filed or that will be filed with the SEC by SCS (when available) through the website maintained by the SEC at <http://www.sec.gov>.

The documents filed by SCS with the SEC also may be obtained free of charge at SCS's website at <https://socialcapitalsuvrettaholdings.com/dnaa> or upon written request to 2850 W. Horizon Ridge Parkway, Suite 200, Henderson, NV 89052.

### **Participants in the Solicitation**

SCS and Akili and their respective directors and executive officers may be deemed to be participants in the solicitation of proxies from SCS's shareholders in connection with the proposed transaction. A list of the names of such directors and executive officers and information regarding their interests in the proposed transaction between Akili and SCS are contained in the proxy statement/prospectus. You may obtain free copies of these documents as described in the preceding paragraph.

### **No Offer or Solicitation**

This communication shall not constitute a solicitation of a proxy, consent or authorization with respect to any securities or in respect of the proposed transaction. This communication shall not constitute an offer to sell or the solicitation of an offer to buy any securities, nor shall there be any sale of securities in any states or jurisdictions in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of such state or jurisdiction. No offering of securities shall be made except by means of a prospectus meeting the requirements of Section 10 of the Securities Act or an exemption therefrom. This press release may be deemed to be solicitation material in respect of the proposed transactions contemplated by the proposed business combination between Akili and SCS.

### **Forward-Looking Statements**

This communication may contain certain forward-looking statements within the meaning of the federal securities laws. These forward-looking statements generally are identified by the words "believe," "project," "expect," "anticipate," "estimate," "intend," "strategy," "future," "opportunity," "plan," "may," "should," "will," "would," "will be," "will continue," "will likely result," and similar expressions and include statements regarding Akili's expectations for EndeavorRx® and digital medicine, the development of its platform and the launch of EndeavorRx®, its partnership with Shionogi and the benefits expected therefrom, including the timing and results expected from its pivotal Phase 3 trial of SDT-001. 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. Many factors could cause actual future events to differ materially from the forward-looking statements in this communication, including but not limited to (i) the risk that the proposed transaction may not be completed in a timely manner or at all, which may adversely affect the price of SCS's securities, (ii) the risk that the proposed transaction may not be completed by SCS's business combination deadline and the potential failure to obtain an extension of the business combination deadline if sought by SCS, (iii) the failure to satisfy the conditions to the consummation of the proposed transaction, including the adoption of the Merger Agreement by the shareholders of SCS and the satisfaction of the minimum cash condition, (iv) the lack of a third party valuation in determining whether or not to pursue the proposed transaction, (v) the inability to complete the PIPE Investment, (vi) the occurrence of any event, change or other circumstance that could give rise to the termination of the Merger Agreement, (vii) the effect of the announcement or pendency of the transaction on Akili's business relationships, operating results, and business generally, (viii) risks that the proposed transaction disrupts current plans and operations of Akili or diverts management's attention from Akili's ongoing business operations and potential difficulties in Akili employee retention as a result of the announcement and consummation of the proposed transaction, (ix) the outcome of any legal

proceedings that may be instituted against Akili or against SCS related to the Merger Agreement or the proposed transaction, (x) the ability to maintain the listing of SCS's securities on a national securities exchange, (xi) the price of SCS's securities may be volatile due to a variety of factors, including changes in the competitive and highly regulated industries in which SCS plans to operate or Akili operates, variations in operating performance across competitors, changes in laws and regulations affecting SCS's or Akili's business, and changes in the combined capital structure, (xii) the ability to implement business plans, forecasts, and other expectations after the completion of the proposed transaction, and identify and realize additional opportunities, (xiii) the ability of Akili to successfully commercialize EndeavorRx<sup>®</sup> and continue to advance its clinical development pipeline, (xiv) the ability to recognize the anticipated benefits of the proposed transaction, which may be affected by, among other things, competition, the ability of the combined company to grow and manage growth profitably, maintain relationships with customers and suppliers and retain its management and key employees, (xv) the evolution of the markets in which Akili competes, (xvi) the ability of Akili to defend its intellectual property and satisfy regulatory requirements, (xvii) the costs related to the proposed transaction, (xviii) the impact of the COVID-19 pandemic on Akili's business, (xix) Akili's expectations regarding its market opportunities, (xx) the risk of downturns and a changing regulatory landscape in the highly competitive industry in which Akili operates and (xxi) the timing and results expected from Akili and its partners' clinical trials. The foregoing list of factors is not exhaustive. You should carefully consider the foregoing factors and the other risks and uncertainties described in the "Risk Factors" section of SCS's registration on Form S-1 (File Nos. 333-256723 and 333-257543), SCS's quarterly report on Form 10-Q for the quarter ended March 31, 2022 filed with the SEC on May 16, 2022, the Registration Statement, including those under "Risk Factors" therein, and other documents filed by SCS from time to time with the SEC. These filings identify and address other important risks and uncertainties that could cause actual events and results to differ materially from those contained in the 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 Akili and SCS assume no obligation and do not intend to update or revise these forward-looking statements, whether as a result of new information, future events, or otherwise. Neither Akili nor SCS gives any assurance that either Akili or SCS, or the combined company, will achieve its expectations.

---

### **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 those statements that relate to the Phase 3 study of Akili's SDT-001 to be conducted by Shionogi and expectations related to the timing of results from the study, Akili's proposed business combination transaction with Social Capital Suvretta Holdings Corp. I, and Akili's and PureTech's 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.

**Contact:**

**PureTech**

Public Relations

[publicrelations@puretechhealth.com](mailto:publicrelations@puretechhealth.com)

Investor Relations

[IR@puretechhealth.com](mailto:IR@puretechhealth.com)

**EU Media**

Ben Atwell, Rob Winder

+44 (0) 20 3727 1000

[ben.atwell@FTIconsulting.com](mailto:ben.atwell@FTIconsulting.com)

**U.S. Media**

Nichole Sarkis

+1 774 278 8273

[nichole@tenbridgecommunications.com](mailto:nichole@tenbridgecommunications.com)

This information is provided by Reach, the non-regulatory press release distribution service of RNS, part of the London Stock Exchange. Terms and conditions relating to the use and distribution of this information may apply. For further information, please contact [rns@lseg.com](mailto:rns@lseg.com) or visit [www.rns.com](http://www.rns.com).

Reach is a non-regulatory news service. By using this service an issuer is confirming that the information contained within this announcement is of a non-regulatory nature. Reach announcements are identified with an orange label and the word "Reach" in the source column of the News Explorer pages of London Stock Exchange's website so that they are distinguished from the RNS UK regulatory service. Other vendors subscribing for Reach press releases may use a different method to distinguish Reach announcements from UK regulatory news.

RNS may use your IP address to confirm compliance with the terms and conditions, to analyse how you engage with the information contained in this communication, and to share such analysis on an anonymised basis with others as part of our commercial services. For further information about how RNS and the London Stock Exchange use the personal data you provide us, please see our [Privacy Policy](#).

END

NRASDDESFESEIOW