

# PureTech Founded Entity Akili Announces American Journal of Psychiatry Publication of Data Demonstrating its Digital Therapeutic AKL-T03 Improves Cognitive Impairments in Adults with Major Depressive Disorder When Combined with Antidepressant Medication

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## **PureTech Founded Entity Akili Announces *American Journal of Psychiatry* Publication of Data Demonstrating its Digital Therapeutic AKL-T03 Improves Cognitive Impairments in Adults with Major Depressive Disorder When Combined with Antidepressant Medication**

*AKL-T03 showed a statistically significant improvement in sustained attention compared to control intervention*

*AKL-T03 is built on the same technology engine as Akili's digital therapeutic EndeavorRx, which has been cleared by the U.S. Food and Drug Administration (FDA) for use in children with ADHD (see full indication below)*

[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 cognitive medicine company improving health through game-changing technologies, today announced that the *American Journal of Psychiatry* has [published](#) findings from the STARS-MDD clinical trial evaluating Akili's AKL-T03 digital therapeutic as a potential treatment for attention impairments in adults with major depressive disorder (MDD) when used alongside antidepressant medication.

More than 16 million people in the United States are living with MDD.<sup>1</sup> Despite the positive benefits of antidepressant therapy on mood, most pharmacologic treatments provide little or no benefit on cognitive impairments in patients with MDD.<sup>2,3,4</sup> Many patients with MDD who have responded to antidepressant treatment continue to report cognitive challenges, including difficulties concentrating, decision making, slowed thinking, and forgetfulness, which have been shown to have an impact on daily activities, like education and work.<sup>5</sup>

The STARS-MDD study enrolled 80 adults, ages 25-55, who were stably treated with an antidepressant medication yet were still experiencing mild to moderate symptoms of depression as well as cognitive impairments. Patients were randomized 1:1 to AKL-T03 or a digital control designed to have an equal expectation of benefit. Results of the study demonstrated that the addition of AKL-T03 to antidepressant therapy significantly improved sustained attention in

adults diagnosed with MDD compared to the control ( $p=0.005$ ), as measured by the Test of Variables of Attention (TOVA), which is a computerized test cleared by FDA to assess attention deficits and evaluate the effects of interventions in ADHD.

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

**The American Journal of Psychiatry Publishes Data Demonstrating Akili Interactive's Digital Therapeutic AKL-T03 Improves Cognitive Impairments in Adults with Major Depressive Disorder When Combined with Antidepressant Medication**

*AKL-T03 showed a statistically significant improvement in sustained attention compared to control intervention*

*AKL-T03 is built on the same technology engine as Akili's digital therapeutic EndeavorRx, which has been cleared by the U.S. Food and Drug Administration (FDA) for use in children with ADHD (see full indication below)*

BOSTON, Mass - April 12, 2022 - Akili Interactive ("Akili"), a leading cognitive medicine company improving health through game-changing technologies, today announced that the *American Journal of Psychiatry* has [published](#) findings from the STARS-MDD clinical trial evaluating Akili's AKL-T03 digital therapeutic as a potential treatment for attention impairments in adults with major depressive disorder (MDD) when used alongside antidepressant medication.

More than 16 million people in the United States are living with MDD.<sup>1</sup> Despite the positive benefits of antidepressant therapy on mood, most pharmacologic treatments provide little or no benefit on cognitive impairments in patients with MDD.<sup>2,3,4</sup> Many patients with MDD who have responded to antidepressant treatment continue to report cognitive challenges, including difficulties concentrating, decision making, slowed thinking, and forgetfulness, which have been shown to have an impact on daily activities, like education and work.<sup>5</sup>

"Society is facing a growing mental health crisis, with depression rates in the U.S. increasing about 20% during the pandemic. While mood symptoms are most often associated with MDD, equally concerning are the frequent associated cognitive impairments," said Richard Keefe, Ph.D., Professor of Psychiatry at Duke University Medical Center, and primary investigator of the study. "More than ever, we need safe and effective ways to support these patients - new tools that can be easily and broadly accessed. Based on the results of this study, AKL-T03 has the potential to play a meaningful role in the treatment of MDD patients."

The STARS-MDD study enrolled 80 adults, ages 25-55, who were stably treated with an antidepressant medication yet were still experiencing mild to moderate symptoms of depression as well as cognitive impairments. Patients were randomized 1:1 to AKL-T03 or a digital control designed to have an equal expectation of benefit. Results of the study demonstrated that the addition of AKL-T03 to antidepressant therapy significantly improved sustained attention in adults diagnosed with MDD compared to the control ( $p=0.005$ ), as measured by the Test of Variables of Attention (TOVA), which is a computerized test cleared by FDA to assess attention deficits and evaluate the effects of interventions in ADHD.

No treatment-related serious adverse events were reported, and two patients (5.5%) reported headaches following treatment with AKL-T03. Results from the STARS-MDD study were first presented at the 58th Annual Meeting of the American College of Neuropsychopharmacology (ACNP) and are consistent with those of prior research of Akili's study of AKL-T01 in patients with MDD, published in *Translational Psychiatry*.<sup>6</sup>

"Addressing cognitive impairments associated with depression has been an area of interest from healthcare professionals and companies over recent years, yet options remain limited for patients," said Anil S. Jina M.D., Chief Medical Officer of Akili. "Akili's technology is designed to target specific neural networks related to attention function

and this study demonstrates the important role it could play in the treatment of patients with cognitive dysfunction in depression."

AKL-T03 is an investigational medical device which has not been cleared by FDA. It is built on Akili's SSME™ technology engine, which is designed to address impairments in attention independent of disease. SSME presents specific sensory stimuli and simultaneous motor challenges designed to target the fronto-parietal cortex, an area of the brain which plays a key role in attention function. This is the same technology embedded in AKL-T01, which has been branded as EndeavorRx® and cleared by FDA to treat attention symptoms in children ages 8-12 diagnosed with ADHD (see full indication below). AKL-T03 was adapted from AKL-T01 with a new game interface designed specifically for an adult patient population.

### **About STARS-MDD**

The Software Treatment for Actively Reducing the Severity of Cognitive Deficits in Major Depressive Disorder (STARS-MDD) study (NCT03310281) is a randomized, double-blind, controlled study designed to assess the safety and efficacy of AKL-T03 versus an expectation-matched digital control intervention in an at-home setting. The study enrolled 80 adult patients between the ages of 25 and 55 with a confirmed diagnosis of MDD according to DSM-5 criteria and confirmed via the Mini International Neuropsychiatric Interview, version 7.0.2. Other key inclusion criteria included confirmation of a score between 14 and 22 on the 17-item Hamilton Depression Rating Scale (HAM-D) during the screening phase (day -28) and at baseline (day 0) and a symbol coding T-score  $\leq 50$  on the Brief Assessment of Cognition. Participants were required to have been on antidepressant medication for  $\geq 8$  weeks prior to screening/baseline with a stable dosage for  $\geq 4$  weeks prior to baseline. Patients were randomized 1:1 to AKL-T03 or a digital control, both of which were administered using Apple iPad mini 2 tablets. Participants in the AKL-T03 arm were instructed to complete five sessions, at least five days per week for six weeks, for a total of approximately 25 minutes of game-play per day. The software automatically locked after the five sessions were completed, to preclude excessive use of the intervention. Participants assigned to the control arm also were instructed to complete 25 minutes of game-play for at least five days per week for six weeks; this software also automatically locked after 25 minutes. The primary endpoint was a change from baseline in cognitive performance following AKL-T03 intervention compared with the control group, as measured by change in sustained attention using the TOVA reaction time to rare target stimuli, normalized by age and sex. The TOVA is a validated computerized continuous performance test of attention and inhibitory control. Change from baseline scores from the first half of the TOVA between day 0 (baseline) and day 42 (study exit) was compared between the two intervention groups.

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

EndeavorRx® is indicated to improve attention function as measured by computer-based testing in children ages 8 to 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. EndeavorRx associated adverse events in clinical trials included frustration (6.1%), headache (1.3%), dizziness (0.6%), emotional reaction (0.4%), nausea (0.4%), and aggression (0.2%). 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. To learn more about EndeavorRx®, please visit [EndeavorRx.com](https://www.EndeavorRx.com).

### **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.

On January 26, 2022, Akili entered into a definitive agreement to become publicly traded via a merger with Social Capital Suvretta Holdings Corp. I (Nasdaq: DNAA), a special purpose acquisition company. The transaction is expected to close in mid-2022, subject to satisfaction of the closing conditions, after which Akili will be listed on the Nasdaq stock market under the new ticker symbol "AKLI."

For more information, please visit [www.akiliinteractive.com](http://www.akiliinteractive.com).

### **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 preliminary prospectus and proxy statement of SCS, referred to as a proxy statement/prospectus. The Registration Statement has not yet become effective. When available, a final proxy statement/prospectus will be sent to all SCS shareholders. SCS will also file other documents regarding the proposed transaction with the SEC. 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 with respect to the proposed transaction between Akili and SCS. 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. 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® 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 and (xx) the risk of downturns and a changing regulatory landscape in the highly competitive industry in which Akili operates. 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 annual report on Form 10-K for the year ended December 31, 2021 filed with the SEC on March 24, 2022, the Registration Statement on Form S-4, 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.

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### **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 25 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 Half Year 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 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](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 AKL-T03, Akili's SSME™ technology engine, expectations around EndeavorRx, the proposed business combination agreement between Akili and Social Capital Suvretta Holdings Corp. I (Nasdaq: DNAA) or matters related thereto, the competitive environment in which Akili operates, and Akili 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, 2020 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.

<sup>1</sup> [Anxiety and Depression Association of America](#)

<sup>2</sup> Keefe RSE, McClintock SM, Roth RM, Doraiswamy PM, Tiger S, Madhoo M: Cognitive effects of pharmacotherapy for major depressive disorder: A systematic review. J Clin Psychiatry 2014; 75(8): 864-876. <https://doi.org/10.4088/jcp.13r08609>

<sup>3</sup> Knight MJ, Mills NT, Baune BT: Contemporary methods of improving cognitive dysfunction in clinical depression. Expert Rev Neurother 2019; 19(5):431-443. <https://doi.org/10.1080/14737175.2019.1610395>

<sup>4</sup> McIntyre R, Harrison J, Loft H, Jacobson W, Olsen CK: The effects of vortioxetine on cognitive function in patients with major depressive disorder: A meta-analysis of three randomized controlled trials. Int J Neuropsychopharmacol 2016; 19(10):pyw055. <https://doi.org/10.1093/ijnp/pyw055>

<sup>5</sup> Gonda X, Pompili M, Serafini G, Carvalho A, Rihmer Z, Dome P: The role of cognitive dysfunction in the symptoms and remission from depression. Ann Gen Psychiatry 2015; 14:27. <https://doi.org/10.1186/s12991-015-0068-9>

<sup>6</sup> Gunning F, Anguera J, Victoria L, [Areán P](#): A digital intervention targeting cognitive control network dysfunction in middle age and older adults with major depression, Translational Psychiatry 2021. <https://www.nature.com/articles/s41398-021-01386-8>

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