



# PureTech Founded Entity Akili Announces the Journal *Lupus* Publishes Investigator-Initiated Study Results Demonstrating Improved Executive Function in Patients with Systemic Lupus Erythematosus Following Use of AKL-T01 Product Candidate

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## **PureTech Founded Entity Akili Announces the Journal *Lupus* Publishes Investigator-Initiated Study Results Demonstrating Improved Executive Function in Patients with Systemic Lupus Erythematosus Following Use of AKL-T01 Product Candidate**

*Data show correlation between targeted activity in the brain and improvement in motor speed and executive function, providing further validation of Akili's technology platform and its potential to improve select cognitive impairments across different indications*

*Data also offer preliminary evidence of Akili's EVO™ Monitor's ability to provide rapid mobile assessment of cognitive function*

[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 publication of full data from a randomized, unblinded study conducted by National Jewish Health and the University of Colorado School of Medicine Departments of Neurology, Psychiatry and Rheumatology that evaluated the ability of Akili's digital therapeutic AKL-T01 to improve cognitive dysfunction in patients diagnosed with Systemic Lupus Erythematosus (SLE). Data from the study show that AKL-T01 resulted in significant improvement in motor speed and executive functions. The study results were published in the medical journal [Lupus](#).

In the randomized, unblinded study of 60 SLE patients aged 18-65, participants showed a high adherence to the 4-week AKL-T01 treatment and showed significant improvement in visuomotor speed (Trail Making A,  $p=0.025$ ) and cognitive flexibility/sequencing (Trail Making B,  $p=0.018$ ) compared to the no contact control group. Further, the study investigated the ability of the product EVO™ Monitor<sup>1</sup>, built on the same technology platform, to serve as a rapid mobile assessment of cognitive function.

At baseline, the multitasking threshold (reaction time difference between single tasking and multitasking) from EVO™ Monitor was associated with performance on tasks of cognitive flexibility and psychomotor speed (Trail Making B,  $r=-0.37$ ,  $p=0.001$  and WAIS-IV coding,  $r=0.30$ ,  $p=0.02$ ). At follow up, the treatment group also demonstrated significant

improvement in EVO™ Monitor compared to the control group (p=0.001). No additional between groups differences were found in other neuropsychological, behavioral, or health outcomes.

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

**The Journal *Lupus* Publishes Investigator-Initiated Study Results Demonstrating Improved Executive Function in Patients with Systemic Lupus Erythematosus Following Use of Akili's AKL-T01 Product Candidate**

*Data show correlation between targeted activity in the brain and improvement in motor speed and executive function, providing further validation of Akili's technology platform and its potential to improve select cognitive impairments across different indications*

*Data also offer preliminary evidence of EVO™ Monitor's ability to provide rapid mobile assessment of cognitive function.*

**BOSTON, Mass. - July 14, 2022** - Akili Interactive Labs, Inc. ("Akili"), a leading digital medicine company, today announced the publication of full data from a randomized, unblinded study conducted by National Jewish Health and the University of Colorado School of Medicine Departments of Neurology, Psychiatry and Rheumatology that evaluated the ability of Akili's digital therapeutic AKL-T01 to improve cognitive dysfunction in patients diagnosed with Systemic Lupus Erythematosus (SLE). Data from the study show that AKL-T01 resulted in significant improvement in motor speed and executive functions. The study results were published in the medical journal [Lupus](#).

Approximately 1.5 million people in the United States are living with SLE.<sup>2</sup> Cognitive dysfunction occurs in 20% to 80% of patients with SLE<sup>3</sup>, twice the prevalence of the general population,<sup>4</sup> and substantially impacts their quality of life<sup>5</sup>.

In the randomized, unblinded study of 60 SLE patients aged 18-65, participants showed a high adherence to the 4-week AKL-T01 treatment and showed significant improvement in visuomotor speed (Trail Making A, p=0.025) and cognitive flexibility/sequencing (Trail Making B, p=0.018) compared to the no contact control group. Further, the study investigated the ability of the product EVO™ Monitor<sup>1</sup>, built on the same technology platform, to serve as a rapid mobile assessment of cognitive function.

At baseline, the multitasking threshold (reaction time difference between single tasking and multitasking) from EVO™ Monitor was associated with performance on tasks of cognitive flexibility and psychomotor speed (Trail Making B, r=-0.37, p=0.001 and WAIS-IV coding, r=0.30, p=0.02). At follow up, the treatment group also demonstrated significant improvement in EVO™ Monitor compared to the control group (p=0.001). No additional between groups differences were found in other neuropsychological, behavioral, or health outcomes.

"Cognitive difficulties such as attention and executive function are linked to a number of autoimmune diseases, yet there are limited assessments and few interventions to support them," said Anil S. Jina M.D., Chief Medical Officer of Akili. "The results of this study in patients with SLE are consistent with the cognitive improvements seen in other studies after using our digital therapeutic. We are excited to see this continued validation of our technology platform as we advance our pipeline to deliver clinically meaningful cognitive and quality-of-life improvements across patient populations."

AKL-T01 is delivered through an action video game experience. The 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 is built on Akili's Selective Stimulus Management Engine (SSME™), its most advanced proprietary therapeutic engine, designed to target cognitive impairment at its source in the brain.

SSME has been clinically validated across more than 20 research, proof-of-concept and pivotal clinical studies in a number of different disease areas to validate the efficacy and safety of Akili's digital therapeutic solutions for the treatment of cognitive impairments, including ADHD, multiple sclerosis (MS), and Autism Spectrum Disorder (ASD).

### **Study Design**

This was a randomized, unblinded study of 60 SLE patients aged 18-65. Study participants completed baseline neuropsychological tests (of attention, psychomotor speed, and executive function), a tablet-based digital assessment (EVO™ Monitor), and biobehavioral measures. The patients were randomized into treatment SLE (n=30) or no contact control SLE (n=30) groups, and returned four weeks later for follow-up cognitive, EVO Monitor, and biobehavioral testing. The SLE treatment group was trained on a tablet-based digital treatment (AKL-T01) and were instructed to complete 5 sessions at least 5 days per week for 4-weeks for a total of approximately 25 minutes of gameplay per day.

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

### **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 and the benefits expected therefrom. 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 ability of Akili to successfully commercialize EndeavorRx® and continue to advance its clinical development pipeline, (ii) the ability of Akili to maintain relationships with customers and suppliers and retain its management and key employees, (iii) the evolution of the markets in which Akili competes, (iv) the ability of Akili to defend its intellectual property and satisfy regulatory requirements, (v) the impact of the COVID-19 pandemic on Akili's business, (vi) Akili's expectations regarding its market opportunities and (vii) 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. 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 assumes no obligation and does not intend to update or revise these forward-looking statements, whether as a result of new information, future events, or otherwise. Akili does not give any assurance that it 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 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 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.

<sup>1</sup> EVO™ Monitor incorporates a proprietary multi-tasking assessment into a state-of-the-art mobile video game-like platform, which deploys modern video game graphics, engaging reward loops, and real-time adaptive mechanics to dynamically personalize difficulty in order to assess the user's ability.

<sup>2</sup> <https://www.lupus.org/resources/lupus-facts-and-statistics>.

<sup>3</sup> Hanly, JG, Harrison, MJ. Management of neuropsychiatric lupus. Best Pract Res Cl Rh 2005; 19: 799-821.

<sup>4</sup> Ainiala, H, Loukkola, J, Peltola, J. The prevalence of neuropsychiatric syndromes in systemic lupus erythematosus. Neurology 2001; 57: 496-500.

<sup>5</sup> Mendelsohn S, Khoja L, Alfred S et al. Cognitive impairment in systemic lupus erythematosus is negatively related to social role participation and quality of life: a systematic review. Lupus 2021, 30:1617-1630

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