



PureTech Founded Entity Akili Announces Positive Results from Shionogi's Phase 3 Clinical Trial of Localized Version of Akili's EndeavorRx® for Pediatric ADHD Patients in Japan

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Japanese Product Now Under Review for Nationwide Marketing Approval

[PureTech Health plc](#) (Nasdaq: PRTC, LSE: PRTC) ("PureTech" or the "Company"), a clinical-stage biotherapeutics company dedicated to changing the lives of patients with devastating diseases, noted that its Founded Entity Akili, Inc. (Nasdaq: AKLI) announced that its Japanese partner Shionogi & Co. Ltd has submitted Akili's digital therapeutic SDT-001 for marketing approval with the Ministry of Health, Labor, and Welfare. SDT-001 is the Japanese, localized version of Akili's AKL-T01 (marketed as EndeavorRx® in the United States), which has previously been authorized by the U.S. Food and Drug Administration (FDA) as the world's first prescription digital therapeutic for improving attentional functioning in pediatric ADHD patients aged 8 to 17.

"We are pleased by this additional validation of Akili's EndeavorRx," said Eric Elenko, Ph.D., Chief Innovation Officer at PureTech. "This game-changing technology is now poised to address the needs of pediatric patients with ADHD in Japan if approved, and this exciting milestone is yet another example of PureTech's contribution to changing the lives of patients in need."

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

Akili Announces Positive Results from Shionogi's Phase 3 Clinical Trial of Localized Version of Akili's EndeavorRx® for Pediatric ADHD Patients in Japan

Japanese Product Now Under Review for Nationwide Marketing Approval

BOSTON--[Akili](#), Inc. (Nasdaq: AKLI), a leading digital medicine company, today announced that its Japanese partner Shionogi & Co. Ltd has submitted Akili's digital therapeutic SDT-001 for marketing approval with the Ministry of Health, Labor, and Welfare. SDT-001 is the Japanese, localized version of Akili's AKL-T01 (marketed as EndeavorRx® in the United States), which has previously been authorized by the U.S. Food and Drug Administration (FDA) as the world's first prescription digital therapeutic for improving attentional functioning in pediatric ADHD patients aged 8 to 17.

"The latest Japanese clinical trial of our patented, clinically proven technology is an important milestone for many reasons," said Dr. Scott Kollins, Chief Medical Officer at Akili. "It not only further validates the efficacy and safety of EndeavorRx, it also moves us and our international partner SHIONOGI a step closer to making the product available in

Japan. And if approved in Japan, it will provide an effective and safe option in a country where some front line pharmaceutical therapies are not as widely available to pediatric patients with ADHD."

The submission for marketing approval in Japan is based on the favorable results of the Phase 3 clinical trial conducted by SHIONOGI in the country. The trial aimed to evaluate the efficacy and safety of SDT-001 in 164 pediatric ADHD patients aged 6 to 17 who received conventional treatments such as environmental adjustments and psychosocial therapies. The SDT-001 group, undergoing approximately 25 minutes of treatment once daily for 6 weeks (1 cycle), demonstrated statistically significant improvements in the change from baseline in the Attention-Deficit/Hyperactivity Disorder Rating Scale IV (ADHD-RS-IV) Inattention score compared to the control group (continuing conventional treatments) at the 6-week mark ($p < 0.05$), achieving the primary endpoint of the trial. Moreover, statistically significant improvements were observed in the change from baseline in the total ADHD-RS-IV score and the hyperactivity/impulsivity score at the 6-week mark in the SDT-001 group compared to the control group ($p < 0.05$). No safety concerns or serious adverse events related to SDT-001 were observed. Furthermore, symptom improvements were sustained even after two cycles of SDT-001 use, with no safety concerns noted.

About Shionogi & Co. Ltd

SHIONOGI is committed to realizing the SHIONOGI Group Vision of "Building Innovation Platforms to Shape the Future of Healthcare" by transforming into a "Healthcare as a Service (HaaS)" company. While enhancing our strengths as a research-based pharmaceutical company, we aim to provide diverse treatment options beyond medicinal products, including collaborations with external partners, to contribute to improving the quality of life for patients and their families.

About EndeavorRx and EndeavorOTC

Akili's suite of cognitive treatment products for ADHD includes EndeavorRx and EndeavorOTC[®]. EndeavorRx is indicated to improve attention function as measured by computer-based testing in children ages 8 to 17 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 trials 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. To learn more about EndeavorRx, please visit [EndeavorRx.com](https://www.endeavorrx.com).

EndeavorOTC is a digital therapeutic indicated to improve attention function, ADHD symptoms and quality of life in adults 18 years of age and older with primarily inattentive or combined-type ADHD. EndeavorOTC utilizes the same proprietary technology underlying EndeavorRx, a prescription digital therapeutic indicated to improve attention function in children ages 8-17. EndeavorOTC is available under the U.S. Food and Drug Administration's current Enforcement Policy for Digital Health Devices for Treating Psychiatric Disorders During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency. EndeavorOTC has not been cleared or authorized by the U.S. Food and Drug Administration for any indications. It is recommended that patients speak to their health care provider before starting EndeavorOTC treatment. No serious adverse events have been reported in any of our clinical studies. To learn more, visit [EndeavorOTC.com](https://www.endeavorotc.com).

About Akili

Akili is pioneering the development of cognitive treatments through game-changing technologies. Akili's 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.

Cautionary Note Regarding Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended. These forward-looking statements generally are identified by the words "believe," "project," "expect," "anticipate," "estimate," "intend," "strategy," "future," "opportunity," "plan," "prepare," "pursue," "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. These forward-looking statements include, without limitation, statements in this press release related to: initial results from the Phase 3 trial conducted by our partner SHIONOGI of our SDT-001 digital therapeutic; our expectations regarding our partner SHIONOGI's plans, and regarding PMDA's potential authorization of, our SDT-001 digital therapeutic in Japan; and our expectation regarding SDT-001's potential, if approved, to provide a safe and effective treatment option to pediatric patients with ADHD in Japan; and other risks identified in our current filings and any subsequent filings made with the Securities and Exchange Commission (SEC). We caution you not to place undue reliance on any forward-looking statements, which speak only as of the date hereof and should not be relied upon as representing our views as of any subsequent date. We disclaim any obligation to publicly update or revise any such statements to reflect any change in expectations or in events, conditions or circumstances on which any such statements may be based, or that may affect the likelihood that actual results will differ from those set forth in the forward-looking statements.

Akili, EndeavorRx, and EndeavorOTC are registered trademarks of Akili, Inc. Other trademarks are trademarks or registered trademarks of their respective owners. All rights reserved.

About PureTech Health

PureTech is a clinical-stage biotherapeutics company dedicated to giving life to new classes of medicine to change the lives of patients with devastating diseases. The Company has created a broad and deep pipeline through its experienced research and development team and its extensive network of scientists, clinicians and industry leaders that is being advanced both internally and through its Founded Entities. PureTech's R&D engine has resulted in the development of 28 therapeutics and therapeutic candidates, including two (Plenity® and EndeavorRx®) that have received both US FDA clearance and European marketing authorization and a third (KarXT) that has been filed for FDA approval. A number of these programs are being advanced by PureTech or its Founded Entities in various indications and stages of clinical development, including registration enabling studies. 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.

For more information, visit www.puretechhealth.com or connect with us on X (formerly Twitter) @puretechh.

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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 related to initial results from the Phase 3 trial conducted by Akili's partner SHIONOGI of Akili's SDT-001 digital therapeutic;

Akili's expectations regarding its partner SHIONOGI's plans and regarding PMDA's potential authorization of Akili's SDT-001 digital therapeutic in Japan; and Akili's expectation regarding SDT-001's potential, if approved, to provide a safe and effective treatment option to pediatric patients with ADHD in Japan, and our future prospects, developments 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, 2022 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.

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