



## PureTech's Independent Affiliate Akili Announces Partnership with Shionogi to Develop and Commercialise Digital Therapeutics in Certain Asian Markets

March 7, 2019

*Akili receives upfront payments totalling \$20 million and has the potential to receive milestone payments for Japan and Taiwan commercialisation of up to an additional \$105 million, in addition to substantial royalties on product sales*

*Akili maintains exclusive global rights to develop and commercialise AKL-T01 and AKL-T02 in all territories outside of Japan and Taiwan*

PureTech Health plc (LSE: PRTC) ("PureTech Health"), an advanced biopharmaceutical company developing novel medicines for dysfunctions of the Brain-Immune-Gut (BIG) axis, today announced that its independent affiliate Akili has entered into a strategic partnership with Shionogi & Co., Ltd. for the commercialisation of two of Akili's digital medicine product candidates, AKL-T01 and AKL-T02, in Japan and Taiwan. AKL-T01 is currently under review with the US Food and Drug Administration (FDA) as a potential digital treatment for children with attention-deficit/hyperactivity disorder (ADHD), and AKL-T02 is in late-stage development as a potential digital treatment for cognitive function and related symptoms in children with Autism Spectrum Disorder (ASD). Under the terms of the agreement, Akili receives upfront payments totalling \$20 million with potential milestone payments for Japan and Taiwan commercialisation of up to an additional \$105 million in addition to substantial royalties. Shionogi will also help fund development costs and commits to a future equity investment in Akili. Akili will maintain exclusive global rights to develop and commercialise AKL-T01 and AKL-T02 in all territories outside of Japan and Taiwan.

Bharatt Chowrira, JD, PhD, President and Chief of Business & Strategy at PureTech Health, said: "Akili has made excellent progress advancing its pipeline of digital medicines through the clinic, with one product candidate under FDA review and several others entering mid- and late-stage development. As Akili prepares for the potential commercialisation of these first-in-class treatments, we're pleased they have chosen to partner with Shionogi, a well-established leader in Japan and Taiwan."

The full text announcement from Akili is as follows:

### **Akili and Shionogi Announce Strategic Partnership to Develop and Commercialise Digital Therapeutics in Key Asian Markets**

*Akili to Create First-of-its-kind International Digital Medicine Development and Commercial Platform*

*Shionogi to Oversee Clinical Development, Sales and Marketing for ADHD and Autism Spectrum Disorder Digital Therapeutics in Japan and Taiwan*

*Upfront and potential milestone payments for Japan and Taiwan commercialisation valued up to \$125 million*

**BOSTON & OSAKA, Japan, March 7, 2019** -- Akili Interactive ("Akili"), a leading digital medicine company creating prescription treatments for people living with cognitive dysfunction and brain-related conditions, and Shionogi & Co., Ltd. ("Shionogi"), a major research-driven pharmaceutical company focused in two therapeutic areas: infectious diseases, and pain/CNS disorders, today announced they have entered into a strategic partnership for the commercialisation of Akili's digital medicines, AKL-T01 and AKL-T02, in Japan and Taiwan. AKL-T01 is currently under review with the U.S. Food and Drug Administration (FDA) as a potential digital treatment for children with attention-deficit/hyperactivity disorder (ADHD); AKL-T02 is currently in late stage development as a potential digital treatment for cognitive dysfunction and related symptoms in children with Autism Spectrum Disorder (ASD). The digital treatments are delivered through immersive action video game experiences.

The partnership leverages each party's distinct expertise to build a novel commercial model and launch the new class of treatment to patients. Under the terms of the agreement, Shionogi will be responsible for regulatory filings and has exclusive rights to the clinical development, sales and marketing of AKL-T01 and AKL-T02 in Japan and Taiwan, which will represent the first such nationwide commitment to digital therapeutics in these territories. Akili will build and maintain control of a newly created Global Access Platform - an R&D and commercial platform including all global product development activities, distribution, technical support services. Akili will also be responsible for data collection and storage in compliance with local laws and regulation related to privacy and the management of personal health information. The Global Access Platform, including its regional platform covering the Japanese and Taiwanese markets, will serve as an independent prescription and patient support system designed specifically for digital therapeutics.

Shionogi makes upfront payments to Akili totalling \$20 million and Akili will be eligible to receive development and commercial milestones of up to \$105 million. In addition, Akili will receive substantial royalties on sales of the products in Japan and Taiwan. Shionogi will also help fund development costs and commits to a future equity investment in Akili. Akili will maintain exclusive global rights to develop and commercialise AKL-T01 and AKL-T02 in all territories outside of Japan and Taiwan.

"Over their 140-year history, Shionogi has been a model of innovation while placing the highest value on patient care. This agreement is indicative of their continued commitment to push the boundaries of medicine and be on the leading edge of next generation therapeutics," said Eddie Martucci, Ph.D., CEO of Akili. "It is critical to Akili that we do everything in our power to maximise long-term growth of our medicines to patients in need, and we could not have found a better partner to work with us to deliver an entirely new treatment model in these territories as we grow our international capabilities."

"ADHD and autism have a significant impact on children and their families in Japan and Taiwan, yet there remains a significant gap in treatment options and access to today's medicines. Akili is a clear leader in digital medicine, and their digital treatment systems represent game-changing solutions to treating these disorders and we look forward to working with them to lead the development of the first digital medicine in Japan and Asia

while bringing new hope to children affected by cognitive dysfunction,” said Dr Isao Teshirogi, President and Chief Executive Officer, Shionogi & Co., Ltd.

#### **About AKL-T01 in Attention-Deficit/Hyperactivity Disorder (ADHD)**

AKL-T01, is an investigational digital medicine being evaluated as a potential prescription treatment for children with ADHD. AKL-T01 is designed to deploy sensory and motor stimuli to target and activate the prefrontal cortex, the area of the brain known to play a key role in cognitive function. The investigational medicine is not delivered through a pill, but rather through a proprietary and captivating video game experience on a smart phone or tablet. Building on multiple published clinical trials, a multi-centre, randomised, double-blind, active-controlled [pivotal study of AKL-T01](#) in paediatric ADHD has recently been completed. This is the first study of its kind, evaluating a potential new digital medicine as you would a drug to treat disease. AKL-T01 is currently under regulatory review in the U.S. to ensure it meets strict standards for efficacy, safety, and manufacturing before being prescribed by physicians to treat paediatric ADHD patients.

#### **About AKL-T02 in Autism Spectrum Disorder (ASD)**

AKL-T02 is an investigational digital treatment for attention-related function and symptoms in children with ASD. Building on the specific and simultaneous sensory and motor stimuli of AKL-T01, Akili worked with experts in the ASD community to modify AKL-T02 to be suitable for ASD patients. AKL-T02 has been tested in a small, active-controlled study in children with ASD patients who also have significant attention issues. This feasibility study evaluated the impact of the digital treatment on attention abilities and parent reported behavioural symptoms of attention and executive function. Plans are now underway for a larger clinical trial.

#### **About Shionogi**

Shionogi & Co., Ltd. is a major research-driven pharmaceutical company dedicated to bringing benefits to patients based on its corporate philosophy of “supplying the best possible medicine to protect the health and wellbeing of the patients we serve.” Shionogi’s research and development currently target two therapeutic areas: infectious diseases, and pain/CNS disorders. For over 50 years, Shionogi has developed and commercialised innovative oral and parenteral anti-infectives. In addition, Shionogi is engaged in new research areas, such as obesity/geriatric metabolic disease and oncology/immunology. Contributing to the health and quality of life of patients around the world through development in these therapeutic areas is Shionogi’s primary goal. For more details, please visit [www.shionogi.co.jp/en/](http://www.shionogi.co.jp/en/). For more information on Shionogi Inc., the U.S.-based subsidiary of Shionogi & Co., Ltd., headquartered in Florham Park, NJ, USA, please visit [www.shionogi.com](http://www.shionogi.com). For more information on Shionogi Ltd., the UK-based subsidiary of Shionogi & Co. Ltd., headquartered in London, England, please visit [www.shionogi.eu](http://www.shionogi.eu).

#### **About Akili**

Akili is a leading digital medicine company combining scientific and clinical rigor with the ingenuity of the tech industry to reinvent medicine. Akili is pioneering the development of prescription digital treatments with direct therapeutic activity, delivered not through a pill but through a high-quality action video game experience. Akili is advancing a broad pipeline of programs to treat cognitive deficiency and improve symptoms associated with medical conditions across neurology and psychiatry, including ADHD, MDD, ASD and various inflammatory diseases. Akili is also developing complementary and integrated clinical monitors and measurement-based care applications. The Company was co-founded by [PureTech Health](#) (PRTC.L) and is a founding member of the [Digital Therapeutics Alliance](#). For more information on Akili, please visit: [www.akiliinteractive.com](http://www.akiliinteractive.com).

#### **About PureTech Health**

PureTech Health (LSE: PRTC) is an advanced biopharmaceutical company developing BIG medicines for dysfunctions of the Brain-Immune-Gut Axis. The Company has gained deep insights into the connection between these systems and the resulting role in diseases that have proven resistant to established therapeutic approaches. By harnessing this emerging field of human biology, PureTech Health is developing new categories of medicines with the potential to have great impact on people with serious diseases.

PureTech Health is advancing a rich pipeline of innovative therapies with an unbiased, non-binary, and capital efficient R&D model across its affiliates and its internal labs. PureTech’s affiliates include seven clinical-stage platforms with two product candidates that have been filed with the US Food and Drug Administration (FDA) for review and other novel pre-clinical programmes. The PureTech Health pipeline includes ground-breaking platforms and therapeutic candidates that were developed in collaboration with some of the world’s leading experts.

PureTech’s internal research and development is centred on tissue-selective immunomodulation for the treatment of oncology, autoimmune, and CNS-related disorders, with a near-term focus on targeting newly-discovered, foundational immunosuppressive mechanisms in oncology and novel approaches that harness the lymphatic infrastructure.

For more information, visit [www.puretechhealth.com](http://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.

This announcement contains inside information for the purposes of Article 7 of Regulation (EU) 596/2014.