Pear Therapeutics Selected to Participate in the FDA’s Digital Health Software Pre-Cert Pilot Program

BOSTON and SAN FRANCISCO - September 26, 2017 - Pear Therapeutics, the leader in a new era of prescription digital therapeutics, today announced that the company has been selected as one of nine companies to participate in the FDA’s Digital Health Software Pre-Cert Pilot Program. The goal of the pilot program is to leverage the best processes and principles from all nine participants to inform the development of a new digital health regulatory framework. This announcement follows the recent FDA clearance of the company’s lead product reSET® for Substance Use Disorder (SUD), the first prescription digital therapeutic to treat disease.

“We commend the FDA’s Digital Health Innovation Action Plan initiative and the speed with which they are moving towards building a regulatory pathway to bring these important products to patients,” commented Corey McCann, President and Chief Executive Officer of Pear Therapeutics. “We are honored to be at the table with these eight other companies and the FDA as we help write the new chapter on digital health and digital therapeutics.”

The FDA’s Digital Health Software Pre-Cert Pilot Program, which was announced on July 27, 2017, is part of the FDA’s broader Medical Innovation Access Plan. The program supports the principle that digital health technologies can have significant benefits to patients’ lives and to the healthcare system by enabling prevention, treatment, and diagnosis and by helping people to manage chronic conditions outside of conventional healthcare settings. The Pilot Program Group will work towards developing the frameworks for: precertification of organizations developing software products; streamlined reviews by the FDA; and post-market collection of data.

About Pear Therapeutics

Pear Therapeutics is the leader in prescription digital therapeutics. The company’s approach is to integrate clinically-validated software applications with previously approved pharmaceuticals and treatment paradigms to provide better outcomes for patients, smarter engagement and tracking tools for clinicians, and cost-effective solutions for payers. Pear’s lead product, reSET®, is an FDA-cleared 12-week interval prescription therapeutic for Substance Use Disorder to be used as an adjunct to standard, outpatient treatment. Pear’s product development pipeline includes reSET®-O™ for opioid use disorder (OUD) and additional prescription digital therapeutics in schizophrenia (Thrive™), combat posttraumatic stress disorder (reCALL™), general anxiety disorder (reVIVE™), pain, major depressive disorder, and insomnia, for which Pear intends to obtain FDA clearance. For more details, please see www.peartherapeutics.com.

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