PEAR THERAPEUTICS

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Pear Therapeutics Receives Expedited Access Pathway Designation from FDA for reSET-O™ Prescription Digital Therapeutic to Treat Opioid Use Disorder

BOSTON, and SAN FRANCISCO, October 18, 2017—Pear Therapeutics, the leader in prescription digital therapeutics, today announced that it has received an Expedited Access Pathway (EAP) designation from the U.S. Food and Drug Administration (FDA) for its reSET-O™ Prescription Digital Therapeutic, the first of its kind designed for treating Opioid Use Disorder (OUD).

"The opioid epidemic continues to ravage cities and towns across this country with officials estimating even higher numbers of overdoses in 2017," said Corey McCann, M.D., Ph.D., President and Chief Executive Officer of Pear Therapeutics. "With states struggling to provide treatment resources, we firmly believe that prescription digital therapeutics will change the way we address opioid dependence. We applaud the FDA for recognizing the need to bring innovative new treatment options to patients and clinicians and we look forward to closely working with them under the EAP program to accelerate access to reSET-O."

Approximately 11.8 million people aged 12 or older misused opioids in 2016 while the number of opioid-related overdose deaths has quadrupled since 1999 with 91 Americans dying every day from an opioid overdose. Standard of care treatment for patients with opioid use disorder is the combination of medication (what is called opioid replacement therapy, ORT, or medication-assisted treatment, MAT) plus neuro-behavioral treatment. Multi-modal therapy, the combination of medication and neuro-behavioral treatment, although standard of care, is not received by the majority of patients.

reSET-O is the first prescription digital therapeutic intended to treat patients with opioid use disorder (OUD), who are enrolled in outpatient treatment and on buprenorphine opioid replacement therapy (ORT). Clinical trials for reSET-O have demonstrated improved abstinence and increased program retention when used in combination with outpatient treatment and opioid replacement therapy (buprenorphine).

The Expedited Access Pathway program was established for medical devices that aim to address unmet medical needs for life threatening or irreversibly debilitating diseases or conditions. Under the EAP program, the FDA works with device sponsors to try to reduce the time and cost from development to a review decision without changing the FDA's 510(k) requirements for demonstrating substantial equivalence.

reSET-O is not yet available in the United States.

About Prescription Digital Therapeutics

Prescription digital therapeutics are clinically validated, FDA-cleared software applications that demonstrate safety and efficacy in randomized clinical trials to improve patient outcomes. They are designed to enhance clinical outcomes, and where clinically relevant may be combined with current treatment regimens including approved drug or device therapies. Prescription digital therapeutics usually include patient-facing applications, clinical assessment and outcomes tracking, clinician monitoring dashboards and HIPAA-compliant data storage.

About Pear Therapeutics

Pear Therapeutics is the leader in FDA-cleared 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 (SUD) 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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