Pear Therapeutics Secures FDA Breakthrough Device Designation for Prescription Digital Therapeutic Candidate to Treat Alcohol Use Disorder

FULL TEXT

Pear Therapeutics has received Breakthrough Device Designation from the U.S. Food and Drug Administration (FDA) for its reSET-A PDT product candidate designed for the treatment of alcohol use disorder (AUD).

According to a media release, reSET-A potentially expands Pear's addiction franchise, which includes FDA-authorized products to treat substance use disorder (SUD) and opioid use disorder (OUD). This is the second such Breakthrough Device Designation received by Pear, following the designation awarded for reSET-O, the first ever for a PDT, which was for the treatment of OUD.

"We believe that PDTs can bring effective, evidence-based treatments for alcohol use disorder to many more people and in doing so help address the public health burden of AUD," said Yuri Maricich, Pear's Chief Medical Officer. "We applaud FDA for recognizing the need to bring safe, effective, and innovative treatment options to patients and clinicians and we look forward to working closely with FDA under the Breakthrough Devices Program to gain marketing authorization of our AUD-only PDT product candidate."

More information:

www.peartherapeutics.com

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