Pear Announces Health Equity Data Showing Similar Engagement with reSET-O® Across US Geographic Regions Presented at APA Annual Meeting

May 24, 2022

- *Results demonstrate that reSET-O®, the only FDA-authorized prescription digital therapeutic (PDT) for the treatment of opioid use disorder (OUD), reached patients across a broad range of geographies, from urban to rural*[1]
- *Results suggest PDTs may enable broader access to treatment and help address health equity and health care disparities*[1]

BOSTON--(BUSINESS WIRE)--May 24, 2022-- Pear Therapeutics, Inc. (Nasdaq: PEAR), the leader in developing and commercializing software-based medicines called prescription digital therapeutics (PDTs), today announced study data that found similar engagement with reSET-O®, the only FDA-authorized PDT for the treatment of opioid use disorder (OUD), among patients across a broad range of US geographic regions, including urban and rural. The results were presented as a poster at the American Psychiatric Association (APA) Annual Meeting held May 21-25, 2022 in New Orleans, Louisiana, and virtually June 7-10, 2022.[1]

“The theme of this year’s APA Annual Meeting, Social Determinants of Mental Health, speaks to the impact that where people live can have on mental health and opioid use disorder. That’s why it’s also important to evaluate associations between geographic regions in the US and levels of engagement with treatment like prescription digital therapeutics,” said Yuri Maricich, MD, MBA, Chief Medical Officer, Pear Therapeutics. “These results suggest reSET-O may enable access to behavioral treatments for OUD across geographic areas, which can help address health equity for those seeking recovery.”

The study assessed a database of de-identified data from 5,263 patients with OUD who completed at least one lesson in a 12-week course of treatment with reSET-O to determine levels of engagement across geographic subgroups (metropolitan, n=2,904; metro commuting, n=709; micropolitan, n=1,081; small town, n=300; rural, n=269). Results reflect levels of engagement with reSET-O were similar for patients with OUD across geographies.[1] Specifically:

- Median days active in the PDT: 21 (metropolitan), 23 (metro commuting), 23 (micropolitan), 23 (small town), 22 (rural)[1]
- Median lessons completed: 25 (metropolitan), 28 (metro commuting), 28 (micropolitan), 27 (small town), 27.5 (rural)[1]
- Patients retained during weeks 9-12 of treatment (defined as any activity in the app): 76% (metropolitan), 79% (metro commuting), 80% (micropolitan), 79% (small town), 78% (rural)[1]

For more information and to view the presentation, please visit https://www.psychiatry.org.

reSET-O Important Safety Information

Indications for Use

reSET-O is intended to increase retention of patients with Opioid Use Disorder (OUD) in outpatient treatment by providing cognitive behavioral therapy, as an adjunct to outpatient treatment that includes transmucosal buprenorphine and contingency management, for patients 18 years or older who are currently under the supervision of a clinician. reSET-O is indicated as a prescription-only digital therapeutic.

Important Safety Information:

Warnings: reSET-O is intended for patients whose primary language is English with a reading level of 7th grade or above, and who have access to an Android/iOS tablet or smartphone. reSET-O is intended only for patients who own a smartphone and are familiar with use of smartphone apps (applications). Clinicians should not use reSET-O to communicate with their patients about emergency medical issues. Patients should be clearly instructed not to use reSET-O to communicate to their clinician any urgent or emergent information. In case of an emergency, patients should dial 911 or go to the nearest emergency room.

reSET-O is not intended to be used as a stand-alone therapy for Opioid Use Disorder (OUD). reSET-O does not replace care by a licensed medical practitioner and is not intended to reduce the frequency or duration of in-person therapy. reSET-O does not represent a substitution for a patient’s medication. Patients should continue to take their medications as directed by their healthcare provider.

Patients with opioid use disorder experience mental health disease and co-morbid medical problems at higher rates than the general population. Patients with opioid use disorder have higher baseline rates of suicidal ideation, and suicide attempts, and suicide completion. Clinicians should undertake standard of care to monitor patients for medical problems and mental health disease, including risk for harming others and/or themselves.

The long-term benefit of reSET-O has not been evaluated in studies lasting beyond 12 weeks (84 days) in the OUD population. The ability of reSET-O to prevent potential relapse after therapy discontinuation has not been studied.

This Press Release does not include all the information needed to use reSET-O safely and effectively. Please see the Clinician Brief Summary Instructions for reSET-O for more information.

About Pear Therapeutics

Pear Therapeutics, Inc., which is traded on Nasdaq as PEAR, is the parent company of Pear Therapeutics (US), Inc. Pear is the leader in developing and commercializing software-based medicines, called prescription digital therapeutics (PDTs). Pear aims to redefine care through the widespread use of clinically validated software-based therapeutics to provide better outcomes for patients, smarter engagement and tracking tools for clinicians, and cost-effective solutions for payers. Pear has the first end-to-end platform to discover, develop, and deliver PDTs to patients and a pipeline of products and product candidates across therapeutic areas, including the first three PDTs with disease treatment claims from the FDA. Pear's product, reSET®, for the treatment of substance use disorder, was the first PDT to receive marketing authorization from the FDA to treat disease. Pear's second product, reSET-O®, for the treatment of opioid use disorder, was the first PDT to receive Breakthrough Designation. Pear's third product, Somryst® for the treatment of chronic insomnia, was the first PDT submitted through FDA's traditional 510(k) pathway while simultaneously reviewed through FDA's Software Precertification Pilot Program. For more information, visit Pear at www.peartherapeutics.com.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the federal securities laws that are subject to risks and uncertainties and other factors which could cause actual results to differ materially from those expressed or implied by such forward-looking statements. Forward-looking statements generally relate to future events involving, or future performance of, Pear. For example, whether PDTs may enable broader access to treatment and help address health equity and health care disparities, whether reSET-O may enable access to behavioral treatments for OUD across geographic areas, whether reSET-O can help address health equity for those seeking recovery are forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as "may", "can" or variations of them or similar terminology.

These forward-looking statements are based upon estimates and assumptions that, while considered reasonable by Pear and its management are inherently uncertain. Factors that may cause actual results to differ materially from current expectations include, but are not limited to: (i) delay or reluctance by patients and/or providers to adopt, request or use Pear's products, (ii) the possibility that Pear may be adversely affected by other economic, business, regulatory, and/or competitive factors; (iii) the evolution of the markets in which Pear competes; (iv) the impact of the COVID-19 pandemic on Pear's business; (v) changes in applicable laws or regulations; and (vi) other risks and uncertainties set forth in Pear's filings with the SEC (including those described in the Risk Factors section). These filings will identify and address other important risks and uncertainties that could cause actual events and results to differ materially from those contained in the forward-looking statements.

Readers are cautioned not to put undue reliance on forward-looking statements, and Pear assumes no obligation and does not intend to update or revise these forward-looking statements, whether as a result of new information, future events, or otherwise.

References:

1. Heather Shapiro, Robert Gerwien, Keely Boyer & Yuri Maricich (2022). Advancing Health Equity: Evidence That a Prescription Digital Therapeutic for Opioid Use Disorder Enables Healthcare Access Across Geographic Regions. Poster # P6-011. American Psychiatric Association (APA) Annual Meeting, 2022.

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