



## Ninilchik Village Tribe Will Provide Access to Prescription Digital Therapeutics to Help Alaskan Community Treat Rural Patients With Substance and Opioid Use Disorders

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- *The Ninilchik Village Tribe will provide access to Pear's reSET® and reSET-O® with proven outcomes in treating substance use disorder (SUD) and opioid use disorder (OUD) respectively and to support members in recovery*
- *Addition of reSET and reSET-O supports tribal members on their recovery journeys with innovative FDA-authorized treatments via their mobile devices*
- *The collaboration exemplifies Pear's commitment to health access and equity*

**Boston and Ninilchik, Alaska, July 20, 2021** – [Pear Therapeutics, Inc.](#) announced today that the Ninilchik Village Tribe is providing access to Pear's FDA-authorized prescription digital therapeutics (PDTs) reSET® and reSET-O® for the treatment of substance use disorder (SUD) and opioid use disorder (OUD), respectively, at its Ninilchik Community Clinic. The Ninilchik Community Clinic provides health services in the Ninilchik area and is also a source of assistance and referrals to other medical facilities in Alaska. Eligible patients will be prescribed and treated with reSET or reSET-O to help the Ninilchik community expand access to addiction care. This project is supported by the Ninilchik Traditional Council (NTC) through a Substance Abuse and Mental Health Services Administration (SAMHSA) Grant for people in need of prevention, treatment and recovery support for opioid use disorder.

"I see firsthand how incorporating newer technologies as treatment options can help to combat both the limited resources and stigma associated with substance use disorders in our community," said Kathleen Totemoff, MAT Project Director for the Ninilchik Community Clinic. "With the addition of reSET and reSET-O, we are able to offer our patients more flexibility while broadening our scope beyond opioid use disorder. I believe that providing access to these novel FDA-authorized prescribed digital therapeutics will offer a tremendous benefit to our patients, particularly with all of the challenges brought about by the pandemic."

Alaska Natives and tribal communities are disproportionately affected by social issues that are widely recognized as contributing factors to substance abuse, addiction, and overdose. As health and wellbeing are important values for the Ninilchik Village Tribe, reSET and reSET-O will be made available to eligible patients through the clinic's outpatient treatment setting, including its opioid treatment program that also administers transmucosal buprenorphine to prescribe and treat patients.

Dr. Sarah Spencer, the Addiction Medicine Specialist at the Ninilchik Community Clinic, added, "I'm excited that we will be able to offer this access to reSET and reSET-O to our patients. This will allow patients who previously haven't been able to access counseling or other behavioral health supports to get extra support for their recovery from the privacy of their home, right from an app on their phone. The app teaches patients skills from cognitive behavioral therapy to give them skills to address drug cravings, triggers and other symptoms that put them at risk for relapse. It's a unique opportunity that hasn't been available previously in rural Alaska."

reSET and reSET-O have been tested in real-world use and randomized controlled trials, with results published in peer-reviewed medical journals<sup>1-5</sup>. Both products, which are adjunctive to outpatient counselling, provide patients with algorithm-driven cognitive behavioral therapy, fluency training, and contingency management, while clinicians receive access to clinical dashboards to inform in-office and tele visits. reSET is used as a monotherapy for patients 18 years of age or older with substance use disorder and reSET-O is used in combination with transmucosal buprenorphine for patients 18 years of age or older with opioid use disorder.

"We believe the lack of accessibility is a major barrier that keeps Native Alaskans and rurally-located Alaskans from receiving treatment for substance or opioid use disorders," said Julia Strandberg, Chief Commercial Officer of Pear Therapeutics. "We are proud to work with the Ninilchik Community Clinic to provide individuals in recovery with access to evidence-based treatment through their mobile devices anytime, anywhere. Together, we can bring a new level of remote support to help Alaskans who are affected by addiction."

### **About the Ninilchik Village Tribe**

The Ninilchik Village Tribe is the modern Alaska Native tribe located in the southern part of the Kenai Peninsula. Its descendants trace their roots from ancient peoples within its tribal boundaries. The tribe's governing organization, the Ninilchik Traditional Council (NTC), is the presiding body over tribal affairs and maintaining tribal sovereignty.

### **About Pear Therapeutics**

Pear Therapeutics is the leader in prescription digital therapeutics, or PDTs. Pear aims to redefine medicine by discovering, developing, and delivering 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 a pipeline of products and product candidates across therapeutic areas, including the first three PDTs with disease treatment claims from FDA. Pear's lead product, reSET®, for the treatment of substance use disorder, was the first PDT to receive marketing authorization from 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](http://www.peartherapeutics.com).

### **About Prescription Digital Therapeutics (PDTs)**

PDTs, such as Pear's reSET-O digital treatment tool, are a new therapeutic class that uses software to directly treat disease. Like traditional

medicines, PDTs are developed in a GMP-compliant environment, tested in randomized controlled trials demonstrating safety and effectiveness, evaluated and authorized by regulators like FDA, and used under the supervision of a prescribing clinician<sup>6,7</sup>. Unlike traditional medicines, PDTs are designed to collect real world data for use by prescribing clinicians and for population health management by payors and health systems. reSET-O has been tested in real world use and randomized controlled trials with results published in peer-reviewed medical journals.

### **reSET Important Safety Information**

#### **Indications for Use:**

reSET is intended to provide cognitive behavioral therapy, as an adjunct to a contingency management system, for patients 18 years of age and older, who are currently enrolled in outpatient treatment under the supervision of a clinician. reSET is indicated as a 12-week (90 day) prescription-only treatment for patients with substance use disorder (SUD), who are not currently on opioid replacement therapy, who do not abuse alcohol solely, or who do not abuse opioids as their primary substance of abuse.

It is intended to:

- increase abstinence from a patient's substances of abuse during treatment, and
- increase retention in the outpatient treatment program.

#### **Important Safety Information for Clinicians:**

**Warnings:** reSET is intended for patients whose primary language is English with a reading level of 7<sup>th</sup> grade or above, and who have access to an Android/iOS tablet or smartphone. reSET is intended only for patients who own a smartphone and are familiar with use of smartphone apps (applications).

Clinicians should not use reSET to communicate with their patients about emergency medical issues. Patients should be clearly instructed not to use reSET 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 is not intended to be used as a stand-alone therapy for substance use disorder (SUD). reSET does not replace care by a licensed medical practitioner and is not intended to reduce the amount of face-to-face clinician time. reSET 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 substance use disorder experience mental health disease and co-morbid medical problems at higher rates than the general population. Patients with substance use disorder also have higher baseline rates of suicidal ideation, and suicide attempts, and suicide completion. Clinicians should engage in their normal care practices to monitor patients for medical problems and mental health disorders, including risk for harming others and/or themselves.

The long-term benefit of treatment with reSET on abstinence has not been evaluated in studies lasting beyond 12 weeks (90 days) in the SUD population. The ability of reSET to prevent potential relapse after treatment discontinuation has not been studied.

The effectiveness of reSET has not been demonstrated in patients currently reporting opioids as their primary substance of abuse.

This Press Release does not include all the information needed to use [reSET](#) safely and effectively. Please see the [Clinician Brief Summary for reSET](#) for more information.

### **reSET-O Important Safety Information**

#### **Indications for Use:**

reSET-O prescription digital therapeutic is a 12-week (84 day) software application 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 for Clinicians:**

**Warnings:** reSET-O is intended for patients whose primary language is English with a reading level of 7<sup>th</sup> 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.

### **Media and Investors**

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