



## Sandoz and Pear Therapeutics Announce US Launch of reSET-O™ to Help Treat Opioid Use Disorder

January 7, 2019

- *reSET-O™\* is the first US FDA-cleared prescription digital therapeutic for patients with Opioid Use Disorder*
- *Cleared by the FDA in December, reSET-O is available immediately*
- *As part of a broader focus on digital healthcare solutions at Novartis, Sandoz aims to increase patient engagement and improve access to treatment through digital solutions*

**Boston, January 7, 2019** – Sandoz Inc., a Novartis division, and Pear Therapeutics, Inc., announced today the US commercial launch of reSET-O™ for patients with Opioid Use Disorder (OUD). reSET-O, cleared by the US Food and Drug Administration (FDA) in December, is immediately available.

The reSET-O prescription digital therapeutic (PDT) is a 12-week cognitive behavioral therapy intended to be used in addition to outpatient treatment. It includes transmucosal buprenorphine, a commonly used medication to treat opioid addiction, and contingency management designed to provide incentives to reinforce positive behaviors. reSET-O is available by prescription only for patients 18 years or older under the care of a clinician.

“The launch of reSET-O provides an important technology-based treatment option for patients with Opioid Use Disorder and may fundamentally change how they interact with their therapies,” said Richard Francis, CEO, Sandoz. “At Sandoz, we are proud and excited to push the frontiers of medical innovation.”

“Addiction is a chronic and relapsing disease that requires constant support, monitoring and access to treatment,” said Corey McCann, M.D., Ph.D., President and CEO of Pear Therapeutics. “We believe prescription digital therapeutics can transform the way clinicians treat addiction by providing a way for patients to access treatment when and where it’s needed. reSET-O has been clinically proven to increase the likelihood that a patient will remain in treatment, while also providing a way for patients to access treatment anytime, anywhere, under clinician supervision.”

The efficacy of reSET-O was evaluated in a pivotal, randomized trial of 170 patients seeking treatment for OUD, who received supervised buprenorphine treatment paired with a behavior therapy program, either with or without the addition of the Therapeutic Education System (TES), which had equivalent content to reSET-O. The clinical trial showed that reSET-O therapeutic content had an overall retention rate of 82.4 percent through the end of 12 weeks of treatment compared with 68.4 percent overall retention rate for patients who did not use reSET-O.

reSET-O also serves as a training, monitoring and reminder tool for healthcare providers by leveraging the Clinician Dashboard. The dashboard helps clinicians gain deeper insights into their patients’ progress toward recovery, including patient-reported buprenorphine adherence to allow for more transparency during in-person therapy sessions.

When a healthcare provider prescribes reSET-O, the patient is contacted by a patient care specialist and is provided with an access code. The patient then downloads and installs reSET-O on their smartphone or tablet and enters the access code to unlock treatment. After that, the patient can begin working and learning with reSET-O by completing lessons, answering quiz questions, reporting medication usage and reporting substance use, cravings and triggers. All the while, the patient continues to see the clinician in therapy sessions and progress on reSET-O is tracked via the Clinician Dashboard.

Under the terms of a commercial deal [announced](#) in April 2018, Sandoz will lead marketing and commercialization of reSET-O and reSET®\*, Pear’s prescription digital therapeutics for the treatment of Substance Use Disorder and Opioid Use Disorder, respectively. Sandoz launched reSET in November 2018 and now has made reSET-O available to patients in the U.S.

High attrition and relapse rates represent a significant obstacle to providing care to patients with OUD. Therefore, it is important to retain patients in treatment. Retention in treatment is a well-established indicator of successful treatment outcomes for OUD patients<sup>i</sup>. The study data demonstrate that reSET-O significantly improved OUD patient retention rates in outpatient treatment.

For more information about reSET-O, go to [www.resetforrecovery.com](http://www.resetforrecovery.com). To help patients get started with reSET-O, call 1-833-MY-RESET (1-833-697-3738) Monday-Friday, 8am-6pm ET or go to [www.resetconnect.com](http://www.resetconnect.com).

### About Opioid Use Disorder

Every day, approximately 115 Americans die after overdosing on opioids<sup>ii</sup>. The misuse of and addiction to opioids—including prescription pain relievers, heroin, and synthetic opioids—is a serious national crisis that affects public health as well as social and economic welfare. The Centers for Disease Control and Prevention estimates that the total “economic burden” of prescription opioid misuse alone in the United States is \$78.5 billion a year, including the costs of healthcare, lost productivity, addiction treatment, and criminal justice involvement.

### reSET-O™ 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 Mobile Medical Application.

#### Limitation for Use:

reSET-O has not been shown to decrease illicit drug use or improve abstinence in patients with OUD.

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

#### About reSET-O™

The reSET-O™ prescription mobile medical application is a 12-week (84-day) software application. It is limited to persons with a valid prescription from their licensed provider. reSET-O is intended to be used to increase retention of patients with Opioid Use Disorder in outpatient treatment by providing cognitive behavioral therapy, as an adjunct to outpatient treatment that includes transmucosal buprenorphine and contingency management to patients currently under clinician care.

#### Disclaimer

This press release contains forward-looking statements within the meaning of the United States Private Securities Litigation Reform Act of 1995. Forward-looking statements can generally be identified by words such as “launch,” “aims,” “will,” “may,” “believe,” “can,” “could,” “potential,” “pioneering,” “growing,” or similar terms, or by express or implied discussions regarding potential launches, marketing clearances and authorizations, new indications or labeling for reSET-O, reSET, or the other products described in this press release, or regarding potential future revenues from such products or the collaboration with and investment in Pear Therapeutics. Such forward-looking statements are based on our current beliefs and expectations regarding future events, and are subject to significant known and unknown risks and uncertainties. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those set forth in the forward-looking statements. You should not place undue reliance on these statements. There is no guarantee that the collaboration with and investment in Pear Therapeutics will achieve any or all of its intended goals and objectives, or be commercially successful. Neither can there be any guarantee that reSET-O will be successfully launched in the U.S., in the expected time frame, or at all. Nor can there be any guarantee that reSET-O, reSET or the other products described in this press release will be commercially successful in the future. In particular, our expectations regarding such products, and the collaboration with and investment in Pear Therapeutics, could be affected by, among other things, the uncertainties inherent in research and development, including clinical trial results and additional analysis of existing clinical data; regulatory actions or delays or government regulation generally; global trends toward health care cost containment, including government, payor and general public pricing and reimbursement pressures; the particular prescribing preferences of physicians and patients; competition in general, including potential approval of additional competing versions of such products; our ability to obtain or maintain proprietary intellectual property protection; litigation outcomes, including intellectual property disputes or other legal efforts to prevent or limit Sandoz or Pear Therapeutics from marketing its products; general political, economic and industry conditions; safety, quality or production issues; potential or actual data security and data privacy breaches, or disruptions of our information technology systems, and other risks and factors referred to in Novartis AG’s current Form 20-F on file with the US Securities and Exchange Commission. Novartis is providing the information in this press release as of this date and does not undertake any obligation to update any forward-looking statements contained in this press release as a result of new information, future events or otherwise.

#### About Sandoz

Sandoz is a global leader in generic pharmaceuticals and biosimilars. As a division of the Novartis Group, our purpose is to discover new ways to improve and extend people’s lives. We contribute to society’s ability to support growing healthcare needs by pioneering novel approaches to help people around the world access high-quality medicine. Our portfolio of approximately 1000 molecules, covering all major therapeutic areas, accounted for 2017 sales of USD 10.1 billion. In 2017, our products reached well over 500 million patients. Sandoz is headquartered in Holzkirchen, in Germany’s Greater Munich area. Sandoz is on Twitter. Sign up to follow @Sandoz\_global at [http://twitter.com/Sandoz\\_Global](http://twitter.com/Sandoz_Global). Follow our blog at [www.sandoz.com/makingaccessshappen](http://www.sandoz.com/makingaccessshappen).

#### About Pear Therapeutics

Pear Therapeutics is the leader in prescription digital therapeutics. We aim 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 severe psychiatric and neurological conditions. Our lead product, reSET®, treats Substance Use Disorder and was the first prescription digital therapeutic to receive marketing authorization from the FDA to treat disease. Pear’s second product, reSET-O™, for the treatment of Opioid Use Disorder, received marketing clearance from the FDA in December 2018. For more information, visit us at [www.peartherapeutics.com](http://www.peartherapeutics.com).

\* reSET-O™ and reSET® are registered trademarks of Pear Therapeutics, Inc.

#### References:

1. Weisner C et al. Short-term alcohol and drug treatment outcomes predict long-term outcome. Drug and Alcohol Dependence. 2003. 71: 281-294.

2. CDC/NCHS, National Vital Statistics System, Mortality. CDC Wonder, Atlanta, GA: US Department of Health and Human Services, CDC; 2017. <https://wonder.cdc.gov>

**For further information, contact:**

**Novartis Media Relations**

Central media line

+41 61 324 2200

[media.relations@novartis.com](mailto:media.relations@novartis.com)

**Novartis Global Media Relations**

Eric Althoff

+41 61 324 7999

[eric.althoff@novartis.com](mailto:eric.althoff@novartis.com)

**Sandoz US Communications**

Leslie Pott

+1 609 627 5287

[leslie.pott@sandoz.com](mailto:leslie.pott@sandoz.com)

**Sandoz Global Communications**

Chris Lewis

+49 8024 476 1906

[chris.lewis@sandoz.com](mailto:chris.lewis@sandoz.com)

**Novartis Investor Relations**

Central investor relations line: +41 61 324 7944

E-mail: [investor.relations@novartis.com](mailto:investor.relations@novartis.com)

**Central**

Samir Shah

+41 61 324 7944

Pierre-Michel Bringer

+41 61 324 1065

Thomas Hungerbuehler

+41 61 324 8425

Isabella Zinck

+41 61 324 7188

**North America**

Richard Pulik

+1 212 830 2448

Cory Twining

+1 212 830 2407

**Pear Therapeutics**

Amanda Galgay

Pear Therapeutics

617-804-6659

[amanda.galgay@peartherapeutics.com](mailto:amanda.galgay@peartherapeutics.com)

[BACK](#)