Sandoz Inc. and Pear Therapeutics Obtain FDA Clearance for reSET-O™ to Treat Opioid Use Disorder

- reSET-O™ is the first FDA-cleared Prescription Digital Therapeutic (PDT) for patients with Opioid Use Disorder
- Pear Therapeutics is leading the development of a new therapeutic class with two FDA-authorized PDTs and a robust pipeline of therapeutics across disease areas
- Sandoz will lead U.S. commercial launch, anticipated in coming days in Q4
- As part of broader Novartis digital revolution, Sandoz aims to increase patient engagement and improve access to treatment through digital solutions

HOLZKIRCHEN, December 10, 2018 – Sandoz Inc., a division of Novartis, and Pear Therapeutics, Inc., the leader in prescription digital therapeutics, today announced that the U.S. Food and Drug Administration (FDA) has granted clearance for reSET-O™.

reSET-O is intended to increase retention of patients with Opioid Use Disorder (OUD) in outpatient treatment by providing cognitive behavioral therapy (CBT), as an adjunct to outpatient treatment that includes transmucosal buprenorphine (medication-assisted-treatment, or MAT) 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.

“Digital technologies and data science have incredible potential to unlock the next chapter of medical innovation and to help individuals finally take control of their own health in a meaningful way,” said Richard Francis, CEO, Sandoz. “New digital therapeutics such as reSET-O also have the potential to fundamentally change how patients interact with their therapies and thus improve patient outcomes. At Sandoz, we are proud to be a joint pioneer in this exciting new field.”

Under the terms of a commercial deal announced in April 2018, Sandoz will lead marketing and commercialization of reSET-O and reSET®, Pear’s PDT for the treatment of Substance Use Disorder. Sandoz launched reSET in November 2018 and plans to launch reSET-O in the coming days in the U.S.

reSET-O is a 12-week interval PDT for OUD. reSET-O is modeled on the Community Reinforcement Approach (CRA) and engineered to deliver CBT for patients with OUD. reSET-O delivers CRA therapy as a series of interactive therapy lessons. Each therapy lesson is comprised of a cognitive behavioral therapy component and skill-building exercises. Therapy lesson content is delivered primarily via text or audio, and may include videos, animations, and graphics.

reSET-O is intended as an adjunct to standard of care for patients with OUD. It is limited to persons with a valid prescription from their licensed provider. reSET-O supports clinician-patient communication between visits, by providing a means for patients to self-report cravings and triggers, and buprenorphine use/non-use. reSET-O reinforces the importance of using buprenorphine for treatment of OUD.

“Nearly 50,000 drug overdose deaths involving opioids, including prescription pain medications and heroin, took place in the U.S. in 2017,” said Corey McCann, M.D., Ph.D., President and CEO of Pear Therapeutics. “There is an urgent need for new and innovative therapeutics to address this public health epidemic. This groundbreaking decision by the FDA ushers in a new standard for treating
patients with Opioid Use Disorder and it signals a new path for therapeutic software to be used in conjunction with pharmacotherapy to improve efficacy."

More than 80 percent of patients with OUD do not receive or seek out care and only 13 percent of outpatient facilities in the U.S. offer MAT, such as buprenorphine. reSET-O could have the potential to dramatically impact this gap in treatment, by delivering multi-modal therapy in combination with MAT in a way that is designed to be more effective, convenient, and easy to access for patients and clinicians. reSET-O helps to offer standardized and enhanced care for OUD, providing particular benefit in geographies where access to care is currently inconsistent or unavailable.

To support the FDA submission of reSET-O, a National Institute on Drug Abuse–sponsored clinical trial evaluated the therapeutic in 170 patients with OUD over 12 weeks. Patients were randomized to receive either treatment-as-usual (TAU), which consisted of standard clinician interactions in conjunction with buprenorphine, or reSET-O with standard clinician interactions in conjunction with buprenorphine. At the end of the study, patients randomized to reSET-O CBT, when used with outpatient treatment and contingency management, significantly improved retention among patients with buprenorphine plus contingency management treatment experience. Treatment dropout during the 12-week intervention was reduced in the test group compared to the TAU group. This reduction in treatment dropout was significant.

High attrition and relapse rates represent a significant problem 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. The finding that reSET-O significantly improved patient retention rates supports the efficacy of reSET-O in increasing retention of patients with OUD in outpatient treatment.

About Opioid Use Disorder
Every day, approximately 115 Americans die after overdosing on opioids. 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.

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 at Clinician Brief Summary Instructions for reSET-O

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 “pipeline,” “to lead,” “launch,” “anticipated,” “aims,” “will,” “groundbreaking,” “could,” “potential,” “pioneer,” “growing,” “may,” 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. You should not place undue reliance on these statements. 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. 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_Globa at http://twitter.com/Sandoz_Globa. Follow our blog at www.sandoz.com/makingaccesshappen.

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.

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

References:


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