Sandoz and Pear Therapeutics announce launch of reSET® for treatment of patients with Substance Use Disorder

- **reSET® is the first and only FDA-authorized prescription digital therapeutic for Substance Use Disorder (SUD)**
- **Adding reSET to outpatient therapy significantly improved abstinence in substances of abuse and treatment retention compared to standard of care alone**
- **Sandoz and Novartis continue to embrace digital technologies to enhance R&D and deliver better outcomes for patients**

Holzkirchen, November 19, 2018 – Sandoz, a Novartis division, and Pear Therapeutics, Inc., announced today the commercial launch of reSET® for patients with Substance Use Disorder (SUD). reSET, the first and only FDA-authorized prescription digital therapeutic, is immediately available.

Study results from a multicenter, randomized clinical trial showed that reSET, when used with outpatient therapy and contingency management, significantly improved abstinence in substances of abuse and increased retention as compared to outpatient therapy alone. The reSET therapeutic content was validated in a randomized clinical trial through the National Institute of Drug Abuse (NIDA) Clinical Trial Network.

reSET is a 12-week (90-day) prescription digital therapeutic to be used in conjunction with outpatient clinician-delivered care. reSET offers interactive treatment modules that deliver cognitive behavioral therapy and fluency training to reinforce proficiency. Within the clinician dashboard, clinicians can follow patient-reported substance use, cravings, and triggers to facilitate transparency and deeper interaction between patients and clinicians at face-to-face meetings.

“We all have a role to play in helping find solutions that work for patients, families and communities as we fight the substance abuse epidemic,” said Richard Francis, CEO, Sandoz. “Adding reSET to outpatient therapy enhances behaviors associated with recovery. It leverages new technology to help patients improve abstinence in substances of abuse and stay in treatment programs longer than outpatient therapy alone.”

“Patients with Substance Use Disorder deserve access to more effective, convenient, and innovative treatment options,” said Corey McCann, M.D., Ph.D., President and CEO of Pear Therapeutics. “reSET has been clinically validated to significantly improve outcomes for patients, while also providing patients a discreet way to access care when and where they need it. Prescription digital therapeutics will help redefine the treatment of serious diseases like Substance Use Disorder, providing improved patient outcomes, and driving clinical insights for clinicians.”
To support patients and clinicians, Pear Therapeutics has also launched the reSET Connect™ Patient Service Center. A specialist is available to provide access to reSET, walk patients and clinicians through the steps for downloading and using reSET, troubleshoot any issues with reSET, and work with the patient’s insurance company to ensure a seamless treatment experience.

In April, Sandoz entered into a collaboration with Pear Therapeutics, Inc. to commercialize and continue development of reSET – designed to effectively augment clinicians and improve clinical outcomes for patients. The collaboration brought together Sandoz expertise in launching and commercializing treatments with Pear’s leading experience in prescription digital therapeutics design, development, and implementation.

SUD is a chronic, relapsing disease caused by the recurrent use of alcohol or drugs – or both. For people with SUD, treatment has typically meant resource-intensive, face-to-face interactions in a specialized setting. Inconsistent quality in treatment, disparities in payment for behavioral health services, and limited accessibility has led to poor treatment outcomes, including low rates of abstinence and high dropout rates.

This collaboration is part of the Sandoz and Novartis strategic effort to work with innovative digital health leaders to drive the next wave of medical innovation. Sandoz and Novartis are collaborating to develop technologies to monitor patient data in real-time, detect day-to-day behavioral and biological changes in condition, improve patient adherence, and ultimately enhance treatment outcomes by helping patients to take a more active role in their own healthcare.

Pear is a leader in developing prescription digital therapeutics, developing the first FDA-authorized prescription digital mobile medical application with both a safety and effectiveness label to help treat patients with SUD.

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

**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:**

**Warnings:** reSET is intended for patients whose primary language is English 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. reSET does not represent a substitution for a patient’s medication. Patients should continue to take their medications as directed by their healthcare provider.

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

This Press Release does not include all the information needed to use reSET safely and effectively. Please see the full reSET Clinician Directions for Use within the reSET Clinician Dashboard for complete Important Safety Information at https://www.resetforrecovery.com/pdf/reSET%20Brief%20Summary%20Instructions%20Clinician%20Information.pdf

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 “to develop,” “potential,” “pending,” “growing,” “strategy,” “aim,” “may,” “will,” ”investigational,” “launching,” “strategic effort,” “next wave,” or similar terms, or by express or implied discussions regarding potential launches, marketing clearances, new indications or labeling for 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. Nor can there be any guarantee that 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.

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

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.

**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 mental health disorders, severe insomnia, and multiple sclerosis. Our lead product, reSET®, treats Substance Use Disorder (SUD), 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 (OUD), is currently under FDA review with Breakthrough Designation. For more information, visit us at www.peartherapeutics.com.

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