PRESS RELEASE

Harm Reduction Therapeutics Announces that its Naloxone Nasal Spray Met its Primary Endpoints in a Phase 1 Clinical Trial

This successful milestone triggers work on a new drug application of a low cost, over-the-counter (OTC) naloxone product for FDA to review

PITTSBURGH, PA, MARCH 1, 2022 – Harm Reduction Therapeutics (HRT), a 501c3 nonprofit pharmaceutical company, announced today positive results from its pivotal Phase 1 clinical trial of their 3.0 mg naloxone nasal spray (HRT001) in healthy adult volunteers. Results confirmed rapid early absorption of naloxone from HRT001 comparable to the FDA reference listed drug, 0.4 mg intramuscular naloxone.

"The pharmacokinetic results from this trial were exactly what we were aiming for and represent a critical step for our plans to file a New Drug Application to the FDA for OTC naloxone," said Judy Ashworth, MD, HRT's Chief Medical Officer.

"The need for a low-cost OTC naloxone product has never been greater," said John Pinney, HRT's Co-Founder and Chair of its Board of Directors. "We could not sit by and watch as thousands die from lack of access to an affordable OTC naloxone product. We formed HRT as a nonprofit so that we could focus all our efforts on developing, manufacturing, and then commercializing an OTC naloxone nasal spray to provide the least expensive product possible to help save lives during the ongoing opioid epidemic. Our goal is to submit our NDA to the FDA later this year, with an estimated commercial launch by early 2024."

This release discusses investigational uses of an agent in development and is not intended to convey conclusions about efficacy or safety. There is no guarantee that OTC naloxone spray, an investigational product, will successfully complete development or gain FDA approval.

About HRT001 (3.0mg intranasal naloxone)

HRT001 is an intranasal formulation of naloxone (3.0 mg) delivered as an atomized spray (0.1 ml) using a standard unit dose system for single administration. Its tentatively approved tradename is RiVive™.

About the HRT-001-PK02 Phase 1 Clinical Trial

This was a 2-part, phase 1, randomized, open-label, single-dose, crossover study to assess the relative bioavailability and pharmacokinetics of HRT001 intranasal naloxone 3.0 mg relative to 0.4 mg intramuscular naloxone in 36 healthy male and female adult participants. The primary objective was to assess the relative bioavailability of 3.0 mg of HRT001 intranasal naloxone relative to 0.4 mg of intramuscular naloxone. The results indicate that HRT's 3.0 mg intranasal product is bioequivalent to the FDA-approved 0.4 mg intramuscular comparator, at both 2.5 minutes and 5 minutes (the key primary endpoint for the clinical trial) following drug administration.

About Naloxone and Opioid Overdose Crisis

Naloxone is a safe and effective opioid antagonist, originally approved by the FDA in 1971 and has been used for decades by both medical professional and the lay public to successfully reverse opioid overdoses. The Centers for Disease Control reported that 100,000 American lives were lost in 2021 to the ongoing drug overdose epidemic. The American Medical Association, past and the present US Surgeon General, and past directors of the FDA have all called for greater access to naloxone. The FDA itself constructed and tested a draft label for sponsors to use as a preliminary starting point in their own OTC applications. Moreover, multiple peer-reviewed studies have found that broader naloxone distribution is warranted in every U.S. state and would help to save lives that will otherwise be lost to the ongoing epidemic. As deaths have risen from the opioid overdose crisis, the prices of naloxone products have risen as well.

About Harm Reduction Therapeutics, Inc.

Harm Reduction Therapeutics (HRT) is a 501c3 non-profit pharmaceutical company whose mission is to prevent opioid overdose deaths by making low price naloxone available to everyone. Founded in 2017 in response to the severe price and access limits to existing naloxone products, HRT brings together experts in drug development, harm reduction, substance dependence, public health policy, and over-the-counter switches of prescription pharmaceuticals. For more information, please visit www.harmreductiontherapeutics.org.

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