PRESS RELEASE

Over-the-Counter Naloxone One Step Closer as Harm Reduction Therapeutics Initiates a Rolling Submission of its New Drug Application (NDA) to U.S. Food and Drug Administration for RiVive™ (3.0 mg intranasal naloxone) for Emergency Treatment of Opioid Overdose

The completed submission of the 505(b)(2) NDA is anticipated later this year

PITTSBURGH, PA, OCTOBER 11, 2022 – Harm Reduction Therapeutics (HRT), Inc., a 501(c)(3) nonprofit pharmaceutical company whose mission is to prevent opioid overdose deaths by making free or low-cost over-the-counter (OTC) naloxone available to everyone, today announced the filing of the first module of its New Drug Application (NDA) for RiVive (3.0 mg intranasal naloxone), as an OTC emergency treatment for opioid overdose. The module was submitted to the U.S. Food and Drug Administration (FDA) in accordance with HRT's rolling review proposal accepted by the FDA after it granted Fast Track status to the application in July 2022.

The foundation for an OTC, easy-to-use intranasal naloxone product indicated for the emergency treatment of opioid overdose was laid over 50 years ago when the FDA first approved naloxone as safe and effective. However, despite the ongoing opioid epidemic, the prescription status and high cost of naloxone products continues to limit access to this life-saving drug. The Centers for Disease Control reported that a staggering 100,000 American lives were lost in 2021 from drug overdoses[1] and more than 80,000 lives were lost to opioid overdose, in particular.[2] The American Medical Association,[3] as well as the past[4] and the present US Surgeon General,[5] and past directors of the FDA[6] have all called for greater access to naloxone. Moreover, multiple peer-reviewed studies have found that broader naloxone distribution[7] is warranted in every U.S. state and would help to save lives that will otherwise be lost to the ongoing opioid epidemic.

"Our NDA for RiVive is supported by a robust nonclinical program and a pivotal Phase 1 relative bioavailability study demonstrating that RiVive produced a 3-fold higher systemic exposure with comparable early absorption to the reference naloxone product" said Dr. Michael Hufford, Co-Founder and Chief Executive Officer at Harm Reduction Therapeutics. "Moreover, our human factors validation study demonstrated that laypeople were able to administer RiVive in a simulated emergency overdose situation supporting that it will be appropriately used as an OTC product by the vast majority of people who need to administer it to victims of opioid overdose in

order to save lives" he added. HRT has entered into a commercial supply agreement with a contract manufacturer in anticipation of FDA approval and U.S. launch in early 2024.

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About RiVive (HRT001, 3.0mg intranasal naloxone)

Naloxone is a safe and effective opioid antagonist, originally approved by the FDA in 1971[8] and has been used for decades by both medical professionals and the lay public to successfully reverse opioid overdoses.[9,10] 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 Harm Reduction Therapeutics, Inc.

Harm Reduction Therapeutics (HRT), Inc. is a 501(c)(3) non-profit pharmaceutical company whose mission is to prevent opioid overdose deaths by making free or low-cost over-the-counter 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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