PRESS RELEASE

Harm Reduction Therapeutics' New Drug Application for RiVive™ Over-the-Counter Naloxone Nasal Spray Accepted and Granted Priority Review by FDA

Low-cost, over-the-counter naloxone nasal spray advances to FDA review. Approval would increase access to this lifesaving medicine for the emergency treatment of opioid overdose.

PITTSBURGH, PA, DECEMBER 26, 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 nasal spray available to the public, today announced that the FDA has accepted its New Drug Application (NDA) for OTC RiVive (3.0 mg intranasal naloxone) for the emergency treatment of opioid overdose. The RiVive NDA was also granted Priority Review, heralding a long-awaited milestone after public health experts[1] and the FDA[2] called for naloxone to be made available OTC. Harm Reduction Therapeutics expects to hear from the FDA regarding the approval of RiVive by April 28, 2023.

The opioid epidemic is an ongoing national tragedy with over 200 Americans dying daily.[3] As this public health crisis has unfolded, naloxone, which was originally approved by FDA in 1971 to reverse opioid overdoses, has remained an expensive product available by prescription only or through standing orders at pharmacies on a state-by-state basis. Recently, FDA issued a preliminary assessment that certain naloxone products have the potential to be safe and effective for over-the-counter use.[4] Harm Reduction Therapeutics' OTC NDA for RiVive is a direct result of FDA's continuing calls for pharmaceutical companies to bring forward OTC applications for naloxone.

"When we formed Harm Reduction Therapeutics in 2017, we saw the urgent need to develop an OTC naloxone product, an action that no other company had pursued. Now, 5 years later and driven by our success in advancing RiVive toward FDA approval, the public health landscape is beginning to evolve, with OTC naloxone hopefully set to become a reality," said Dr. Michael Hufford, Co-Founder and Chief Executive Officer at Harm Reduction Therapeutics.

Harm Reduction Therapeutics' NDA is supported by a Phase 1 clinical trial demonstrating that RiVive produces a 3-fold higher systemic exposure with comparable early absorption to the reference naloxone product, as well as robust Human Factors Validation work demonstrating that laypeople are able to administer RiVive in a simulated emergency overdose situation. 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 (3.0mg intranasal naloxone)

Naloxone is a safe and effective opioid antagonist, originally approved by the FDA in 1971 and has been used for decades by both medical professionals and the lay public to successfully reverse opioid overdoses.[5,6] RiVive 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.

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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