



Harm Reduction Therapeutics Signs Commercial Supply Agreement for Fast Tracked Naloxone Nasal Spray to Reverse Opioid Overdoses

PITTSBURGH, PA, AUGUST 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 signing of a commercial supply agreement. Under its terms, the contract manufacturer will produce Harm Reduction Therapeutics’ nasal spray, RiVive™ (3.0mg naloxone), for the emergency treatment of known or suspected opioid overdose.

The commercial supply agreement comes after the U.S. Food and Drug Administration (FDA) recently granted Harm Reduction Therapeutics Fast Track designation on July 1, 2022, for their OTC naloxone nasal spray, which is currently in development. 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. However, existing naloxone nasal sprays are costly medications, and access to them is limited to behind-the-counter pharmacy distribution through a prescriber or a Health Department’s standing order.

Since 2017, Harm Reduction Therapeutics has been working on a low-cost, OTC naloxone product to act as a critical tool to begin to stem the loss of life from the U.S. opioid crisis. In anticipation of FDA approval and U.S. launch in early 2024, the contract manufacturer will manufacture RiVive at its US facility.

“We are thrilled to partner with our contract manufacturer on the commercial manufacturing of RiVive. The opioid epidemic is an ongoing national tragedy, and for OTC naloxone to address this unmet need we needed a manufacturing partner with the capability and bandwidth to help make naloxone much more widely and easily accessible to save lives that will otherwise be lost to opioid overdose,” said Bernie Simone, Chief Operating Officer at Harm Reduction Therapeutics.

“This commercial supply agreement and the FDA’s Fast Track designation mark major milestones for Harm Reduction Therapeutics and are significant steps forward in making OTC naloxone a reality,” said Dr. Michael Hufford, Co-Founder and Chief Executive Officer at Harm Reduction Therapeutics.

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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