



## FOR IMMEDIATE RELEASE

### FDA APPROVAL OF RiVIVE™ IS A CRITICAL MILESTONE IN MAKING EMERGENCY TREATMENT OF OPIOID OVERDOSE MORE WIDELY AVAILABLE

- **RiVive™, a naloxone nasal spray that is easy to use, will be available over-the-counter**
- **Unlike other opioid overdose products, Harm Reduction Therapeutics will make RiVive™, which can save lives, available for free or at low breakeven cost**

**PITTSBURGH, PA, JULY 28, 2023** – Harm Reduction Therapeutics (HRT), Inc., a nonprofit pharmaceutical company, announced today that FDA has approved OTC RiVive™ (naloxone HCl nasal spray 3 mg) for the emergency treatment of opioid overdose. This critical milestone will help prevent opioid overdose deaths by making free or low-cost over-the-counter (OTC) naloxone nasal spray available to everyone in the United States.

“We are grateful that FDA granted RiVive approval so we can now achieve what most thought impossible and no other company has: broad delivery of a lower-cost nasal naloxone product without a prescription to save lives that could otherwise be lost to opioid overdose,” said Michael Hufford, PhD, co-founder and chief executive officer of Harm Reduction Therapeutics, Inc.

No company, entity, or individual will profit from sales of RiVive. As a nonprofit pharmaceutical company, HRT is engaging additional funding partners to help make its affordable opioid overdose treatment more accessible. Partners can direct their financial support to further lowering the price of RiVive, making more of it available free to specific U.S. nonprofit harm reduction organizations, and/or helping to increase manufacturing capacity so that more lives can be saved.

Since 2017, more than 290,000 people across the U.S. have died of an opioid overdose.<sup>1</sup> HRT stands behind the principle articulated by the White House and Office of National Drug Control Policy Director Dr. Rahul Gupta that “no one who needs overdose reversal medications should lack access because of costs or availability.”<sup>2</sup>

HRT began manufacturing RiVive at-risk to minimize the typical lag between FDA approval and launch of a new product. As a result, HRT anticipates that RiVive will be available in early 2024 primarily to U.S. harm reduction organizations and state governments for costs lower than other opioid antagonist nasal sprays. HRT is focused on supplying RiVive to communities who need it most and will make at least 200,000 doses (10% of projected initial annual product production) available for free.

RiVive uses an easy-to-use standard unit dose system that can be used in an emergency situation to reverse the life-threatening effects of known or suspected opioid overdose. Each RiVive nasal spray device contains one dose of naloxone. It will be exclusively available in twin packs containing two single-

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<sup>1</sup> [Drug Overdose Death Rates | National Institute on Drug Abuse \(NIDA\) \(nih.gov\)](#)

<sup>2</sup> [Statement from ONDCP Director Dr. Rahul Gupta Regarding White House Meeting on Increasing Access and Affordability of FDA-Approved Overdose Reversal Medications | ONDCP | The White House](#)

dose devices. It is safe to keep administering RiVive every two to three minutes until the person wakes up.

RiVive is currently being produced under a commercial supply agreement with Catalent, a leading global contract development and manufacturing organization, at their facility in Morrisville, North Carolina.

#### **About RiVive™**

RiVive™ (naloxone HCl nasal spray 3 mg) is a novel over-the-counter intranasal formulation of naloxone (3.0 mg) delivered as an atomized spray (0.1 ml) that can save lives. It uses an easy-to-use standard unit dose system for single administration for the emergency treatment of opioid overdose without a prescription. RiVive produces a 3-fold higher systemic exposure with comparable early absorption to the reference naloxone product (0.4 mg delivered via intramuscular injection). Human factors validation work demonstrated that laypeople were able to administer RiVive in a simulated emergency overdose situation. **Warning: when using this product, some people may experience symptoms when they wake up such as shaking, sweating, nausea or feeling angry.** For more information on Drug Facts call toll free (888) 412.7454 or go to [www.harmreductiontherapeutics.org](http://www.harmreductiontherapeutics.org).

#### **About Naloxone**

Naloxone is a safe and effective FDA approved opioid antagonist that has been used for decades to safely and effectively reverse opioid overdoses.<sup>3</sup>

#### **About Harm Reduction Therapeutics, Inc.**

Harm Reduction Therapeutics (HRT), Inc. is a 501(c)(3) nonprofit pharmaceutical company whose single mission is to prevent opioid overdose deaths by making free or low-cost over-the-counter naloxone available to everyone. It is the first nonprofit company to achieve FDA approval of a naloxone nasal spray. 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](http://www.harmreductiontherapeutics.org).

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**Note to Editors:** The approved and official product name is RiVive™ and it should always be so capitalized and trademarked. High quality images of RiVive logos and product package can be found [here](#).

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<sup>3</sup> For example: Avetian, et al. (2018) DOI : 10.1080/03007995.2017.1334637 ; Bennett, et al. (2018) DOI : 10.1080/02791072.2018.1430409; Campbell (2020). ISBN: 978-0262043663; <https://remedyallianceftp.org/pages/history>.