



FOR IMMEDIATE RELEASE

A2A Alliance Pharmaceuticals and Harm Reduction Therapeutics Announce Strategic Partnership to Expand Access to Life-Saving OTC Naloxone 3mg Nasal Spray (RiVive™) to U.S. Federal Entities and Veterans

AUGUST 14, 2024 - A2A Alliance Pharmaceuticals (A2A), a Service-Disabled Veteran-Owned Small Business (SDVOSB), and Harm Reduction Therapeutics (HRT), a 501(c)(3) non-profit organization focused on saving lives that would otherwise be lost to opioid overdose, are pleased to announce a strategic partnership to expand access to RiVive™, an FDA-approved over-the-counter (OTC) 3mg naloxone nasal spray. This collaboration is timely and crucial, as it seeks to put a compassionate dose of life-saving emergency overdose rescue medication into the hands of those most at risk, including the 18.6 million Veterans and underserved communities in the United States. RiVive™ will be available through A2A's comprehensive federal procurement vehicles, including the Federal Supply Schedule (FSS) and Department of Defense (DoD), providing immediate access to all federal entities and beneficiaries.

Partnership Overview

This partnership combines HRT's expertise in harm reduction and the development of the RiVive™ Naloxone 3mg product with A2A's extensive market access within federal markets, leveraging its status as an SDVOSB. Through various federal procurement vehicles, including the Federal Supply Schedule (FSS) and Department of Defense (DoD) contracts, A2A ensures that RiVive™ is readily accessible to all U.S. Federal Entities, including the Veterans Health Administration, Department of Defense, Department of Homeland Security, Indian Health Service, and other federal agencies. The involvement of these procurement vehicles will facilitate the rapid distribution and availability of this critical medication across federal facilities, ensuring that those in need have timely access. This initiative is especially significant as it aligns with the mission to support the health and well-being of Veterans, their families, and all those in need, helping to save lives that might otherwise be lost to opioid overdose.

Call to Action

We call upon all Veterans, federal agency beneficiaries, and the harm reduction community to support this initiative. By advocating for the availability of RiVive™ from elected representatives and U.S. Federal Agencies, you can help ensure that this essential medication reaches those who need it most, particularly our Veterans. Your support can make a significant difference in addressing the opioid crisis and saving lives. We encourage you to learn more about RiVive™ and consider its inclusion in your healthcare toolkit to protect those at risk of opioid overdose.

Statements from Leadership

"We are excited to partner with Harm Reduction Therapeutics to get RiVive™ in the hands of each and every one of my fellow Veterans," said COL(R) Rondal L Turner, President & CEO at A2A Alliance Pharmaceuticals. "Our goal is to ensure that all 18 million Veterans in the United States have immediate access to this life-saving medication. This collaboration is not just about providing a critical tool for opioid overdose intervention; it's about fulfilling our commitment to the health and safety of Veterans. By making RiVive™ readily available, we can help protect our Veterans from the devastating effects of opioid overdoses and provide peace of mind to their families and caregivers."

Michael R. Hufford, PhD, Co-founder and CEO at Harm Reduction Therapeutics, added, "Our goal has always been to make our emergency treatment for opioid overdose accessible to those who need it most, including our Veterans and U.S. Federal Entities. Through our partnership with A2A, we can provide more people with a safe and effective way to reverse an opioid overdose in a dose that saves lives while minimizing the unintended consequences of overdose reversal, like precipitated withdrawal."

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: [RiVive.com](https://www.rivive.com).

FDA Approval and Timely Response to the Crisis

The FDA approval of RiVive™ followed a review process, ensuring that the product met the highest standards of safety and efficacy. This approval is particularly timely given the escalating opioid crisis, which continues to claim thousands of lives annually. The FDA's Fast Track review of RiVive™ highlights the urgent need for accessible opioid overdose reversal solutions, especially in the context of increasing overdose rates. The opioid epidemic has been exacerbated by the availability of potent synthetic opioids like fentanyl, which have significantly increased the risk of overdose. In response, the FDA recognized the critical need for readily available naloxone products with a prescription that can be administered by non-medical personnel in emergency situations. RiVive™ addresses this need with its user-friendly design and effective dosage, making it an essential tool in combating opioid overdoses.

The FDA approval and subsequent release of RiVive™ come at a crucial time when communities, particularly vulnerable populations like Veterans, are in desperate need of reliable overdose prevention measures. The collaboration between A2A Alliance Pharmaceuticals and HRT aims to ensure that this life-saving medication reaches those most at risk, providing a timely and critical response to a public health emergency.

Clinical and Medical Guidance

Naloxone, a safe and effective opioid antagonist, reverses the life-threatening effects of opioid overdose¹. The efficacy of RiVive's™ 3mg dosage effectively counteracts opioid-induced respiratory depression while potentially reducing the risk of precipitating severe withdrawal symptoms. This lower dosage helps prevent exacerbating co-occurring conditions like PTSD and other mental illnesses, which are prevalent among Veterans.

Advantages Over Higher Doses (3mg vs. 4mg/8mg)

Higher doses of naloxone, such as 4mg and 8mg, while effective, are associated with a higher incidence of precipitated withdrawal symptoms. These symptoms can cause significant discomfort and distress, posing additional challenges for non-professional caregivers. RiVive™'s 3mg dose of naloxone mitigates these risks by providing a lower yet effective dose, helping to enable safer management of overdoses, particularly in home settings. The risk of over-administration and severe withdrawal symptoms is minimized, making RiVive™ a compassionate and safe option for Veterans and other at-risk populations.

Suitability for Home Use

The increasing prevalence of opioid use and the associated risk of overdose among Veterans necessitate reliable, user-friendly rescue medications. RiVive™ naloxone HCl nasal spray 3mg is designed for ease of use, making it an ideal option for emergency situations at home. Its lower dosage aligns with the principle of administering the minimal effective dose, ensuring both efficacy and safety. The reduced likelihood of severe reactions provides peace of mind for spouses or caretakers administering the spray in stressful situations.

About A2A Alliance Pharmaceuticals

A2A Alliance Pharmaceuticals is a CVE-SDVOSB pharmaceutical organization dedicated to providing high-quality pharmaceutical products and services to federal markets, with a focus on Veteran health and safety. Utilizing multiple federal procurement vehicles, including the Federal Supply Schedule (FSS) and Department of Defense (DoD) contracts, A2A ensures that critical medications are accessible to all federal entities and beneficiaries. The VA's involvement in distribution to federal entities further ensures that life-saving treatments like RiVive™ are available where they are needed most, across all federal facilities and federal beneficiaries.

About Harm Reduction Therapeutics Inc.

Harm Reduction Therapeutics (HRT) Inc. is an independent 501(c)(3) nonprofit pharmaceutical company dedicated to a singular mission: preventing opioid overdose deaths by providing free or low-cost over-the-counter naloxone to everyone in need. HRT's commitment to this cause is underscored by its efforts to make life-saving medications accessible to all, regardless of economic status.

¹<https://www.samhsa.gov/medications-substance-use-disorders/medications-counseling-related-conditions/opioid-overdose-reversal-medications#:~:text=Naloxone%20is%20a%20medication%20approved,heroin%2C%20morphine%2C%20and%20oxycodone>

Neither Purdue nor any of its creditors receive any revenues, royalties, or profits associated with sales of RiVive™.

Contact Information

For Federal Government and product access: <https://www.a2aalliancepharma.us/>

COL(R) Rondal L Turner, Rondal.turner@A2A-AllianceRx.com, Info@A2A-AllianceRx.com

Media inquiries or funding partner opportunities: Dr. Michael Hufford
mhufford@harmreductiontherapeutics.org

For product information: support@harmreductiontherapeutics.org

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](#).