

Empowering the Warfighter: Resilience Through Innovation

291

BROAD-SPECTRUM THERAPEUTICS FOR VIRAL DISEASES: A MEDICAL COUNTERMEASURE PLATFORM FOR EMERGING THREATS

Repurposing Tranexamic Acid As A Broad Spectrum Antiviral Nasal Spray Against Respiratory Viruses

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As evidenced by the events related to SARS-CoV-2 infections worldwide, there is an urgent need for effective strategies and products to deal with emerging infectious respiratory diseases. A product that also works against the perennial respiratory viruses would be particularly helpful. Existing vaccines and therapeutics have shown good results but gaps still remain which can affect the mission capacity of warfighters. For example, vaccines are not immediately available for novel viruses, and the annual flu vaccines never cover all active flu viruses.

What is needed is an easy to deploy antiviral therapeutic which is threat agnostic/broad-spectrum and that can be used prophylactically as well as after first symptoms. Further, an ideal candidate would act quickly at the initial site of infection and replication. While researching new uses of a known small molecule drug (tranexamic acid (TXA)), Tranexamic Technologies has discovered that TXA is a broad-spectrum antiviral drug that acts very rapidly when delivered topically and has developed a simple nasal spray that can easily be used on demand without the need for intervention by medical personnel. In clinical cases, it has generally resolved symptoms within 24-48 hours when taken early. In the military setting, personnel would return to duty much faster, and spread to others would be reduced and possibly eliminated with prophylactic use.

TXA (as a lysine analog and protease inhibitor) has been safely used for decades for its FDA approved systemic uses (IV and oral) to limit bleeding in certain circumstances and is currently used off label in millions of surgical procedures such as total joint replacement where it has become standard of care. In addition, TXA has become an integral part of life saving treatment of bleeding trauma world-wide including early use on the battlefield. Tranexamic Technologies has developed a novel formulation and delivery method for this extremely safe small molecule drug and our in vitro and in vivo tests have shown excellent inhibition of a wide range of viral infections, including Flu A (H1N1,H3N2,H5N1,H7N9) and Flu B, HSV 1 (including acyclovir resistant strains), HSV-2, HIV-1,EV-D68 and SARS-CoV-2. The nasal spray can be administered prophylactically or at the first sign of symptoms and since it works on host and viral proteins via multiple MOA's (including amino acid deprivation and immunomodulation), it could be the first line of a layered defense against viral threats from natural or man-made origins without diagnosis or increasing the chance of new mutations. Compact and storage stable at ambient temperatures, the nasal spray has been developed with a major U.S. CDMO and is readily scalable and ready for clinical study. Current plans are to conduct a Phase 1-2 challenge trial vs H1N1 in association with NIAID to demonstrate POC, led by the leading authority in the US on this type of trial.

Tranexamic Technologies is seeking DTRA support to advance this important project through clinical study and licensure.