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Readi: An Innovative Synthetic T Cell Vaccine Technology Platform Pairing A Gold Nanoparticle Delivery System With Select Targets From A Ligandome Of Prescreened Pathogen Derived, Naturally Processed & Presented Mhc-i Peptides To Provide Rapid Response Solutions To Combat And Broadly Protect Against Biothreat Pathogens

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The Rapid Emergex Antigen Deployment Initiative (READI) platform is derived from the pairing of an innovative gold nanoparticle delivery system with naturally processed and presented pathogen-derived synthetic peptide antigens, which when united specifically enhances a broadly protective cellular immune response. The READI platform focuses on specific enhancement of the major histocompatibility class I (MHC-I) related adaptive immune subsystem eliciting antigen-specific, functional T cell responses against viral or bacterial pathogens.

Existing countermeasures to infectious biothreats rely on pre- or post-exposure prophylaxis: humoral mediated vaccine solutions and/or antivirals. Emergex's platform specifically targets CD8+ T cell activation and response enhancement. In collaboration with the Biomedical Research Laboratory (BRL) at George Mason University (GMU) the platform has been applied to both viral (alphaviruses, betacoronaviruses, influenza viruses, etc.) and bacterial (Francisella tularensis) pathogens. Immunopeptidomes are first generated to a variety of pathogens, and the resulting ligandome libraries are the naturally processed and presented MHC-I restricted peptides prescreened for highly conserved pathogen derived sequences capable of eliciting broadly protective T cell activation. Prescreened ligandome libraries utilized by READI are the foundation of the preparedness strategy; when a countermeasure is required to a known or unknown infectious threat, selection of approximately 8 to 12 peptide antigens from the ligandome libraries are then paired with the gold nanoparticle delivery system and manufactured using a rapid, fully synthetic process. The resulting T cell adaptive vaccine is fully synthetic, shelf stable, and can be deployed intradermally using microneedle devices.

Emergex utilizes in vitro and in vivo model systems to supplement an immunoproteomics technique to acquire and characterize pathogen immunopeptidomes. These models lend themselves to processing MHC-I specific targets and characterizing immunogenic profiles. The nanoparticle delivery system, a major piece of the READI foundation, has passed extensive preclinical GLP safety and stability studies, including stability of the bio-payload at 37C for up to six months. Additional preclinical data has demonstrated the nanoparticle delivery system exhibits a depot delivery profile with biologically relevant exposure of antigen for an extended period. Emergex's nanoparticle has also demonstrated in preclinical experiments the ability to reduce inflammation, which would foster an ideal priming environment for antigen-specific T cells. The bio-payload has been shown to elicit antigen-specific, functional T cell responses from both the cytotoxic and the memory cell subpopulations.

Emergex's technology, the foundation for the READI, has entered human Phase 1 clinical trials establishing a proof-of-concept for the platform. These studies are demonstrating robust safety profiles with preliminary, positive efficacy data. Furthermore, through an existing collaboration with GMU, the READI platform is being extended to other biothreat pathogens.

The READI platform will offer a broadly protective, rapid response solution to support DTRA's mission and better protect the warfighter by enhancing an under-targeted, naturally occurring subsystem of the immune system. When the foundation for the READI platform is positioned to include strategic ligandome antigen targets then any call for activation will initiate a proven system yielding quick, efficient production of vaccine to counter a known or unknown biothreat.

We would like to thank all our colleagues at Emergex and GMU for their commitment to being a better community member, both locally and worldwide, to support and provide innovative and strategic contributions to the world of science, medicine, and healthcare.