



PRESS RELEASE

Emergex Announces GMP Production of its CD8+ T cell Universal Influenza Vaccine

- *Emergex will manufacture the candidate universal influenza vaccine to cGMP standards for use in Phase I human trials*
- *Emergex's universal influenza vaccine is a radically different approach to inducing influenza immunity by employing the use of a combination of:*
 1. *Highly conserved Class I peptides from non-structural proteins (NSP) representative of pandemic influenza A strains which have occurred since 1918,*
 2. *Class I peptides from a negative sense open reading frame (ORF) that evolved and varied at ~50-year H1N1 pandemic intervals, defining the subsequent imprinted generational immunity.*

Abingdon, Oxon, UK, 28 July 2022 – Emergex Vaccines Holding Limited ('Emergex', or the 'Company'), a clinical stage biotechnology company addressing major global infectious diseases through the development of fully synthetic CD8+ T cell Adaptive Vaccines, announces the manufacture of its universal/pandemic influenza vaccine, ready for Phase I clinical trials.

Emergex has announced an important move into cGMP (ready for human clinical trials) production of their influenza vaccine candidate. Influenza A is a segmented RNA virus and circulates as a quasi-species cloud. Conventional influenza vaccines offer limited efficacy relying upon the production of antibodies to provide immunotherapy. This approach can potentially prevent birth cohort imprinted T cell immunity in children with later life consequences. Emergex's vaccine works differently by prime/activating influenza specific CD8+ T cells that recognise these same peptides when presented on the surface of infected cells and kill the infected cell during the eclipse phase - therefore preventing virion production. The vaccine is designed to induce CD8+ T cells specific to highly conserved parts of the influenza virus from both the positive and negative sense reading frames. This approach has the potential to transform the global approach to influenza and pandemic influenza strategies, removing the requirement for strain specific vaccines and offer extended immune protection and importantly offer protection against future pandemic strains.

Emergex has pioneered T cell vaccination and was the first vaccine to be approved for clinical trials based on inducing a CD8+ T cell response without relying upon antibodies. The first Phase I clinical trials (Dengue and COVID 19) have demonstrated that the platform potential of the vaccine platform in humans. The extension of the vaccine platform to non-canonical reading frames – and targeting viral peptides that are generated in the pioneer round and expressed during the eclipse phase of viral replication and are highly conserved in their nature – marks an important step forward for Emergex and global immunisation strategies.

Type A influenza strains have been responsible for H1N1 pandemics usually on 50-year cycles in contrast to Type B influenza. Localized influenza epidemics of variable severity occur annually worldwide in all age groups, typically during the winter months in temperate climates. These annual epidemics are thought to result in 3 million to 5 million cases of severe illness and approximately 250,000 to 500,000 deaths every year around the world (WHO, 2005).

Laurens Rademacher, Chief Technology Officer at Emergex commented: “Advancing into cGMP production is an important milestone for the Emergex Universal Influenza Vaccine candidate. Having completed preclinical safety and proof of mechanism (POM) efficacy studies, we are now confident this vaccine is ready to be added to our clinical pipeline along with our Dengue and Coronavirus vaccine candidates. By targeting novel and conserved areas of the Influenza virus, we believe that our approach could provide a long-term solution against the global threat of both seasonal and future pandemic Influenza.”

- Ends -

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About Emergex

About Emergex

Emergex, a clinical-stage, privately-held biotechnology company headquartered in Abingdon, UK, with an operating subsidiary in Doylestown, Pennsylvania, USA, is pioneering the development of 100% synthetic T cell Adaptive Vaccines that harness the body's natural T cell immune response to destroy pathogen-infected cells in order to provide protection against some of the world's most pressing health threats: [i] viral infectious diseases, amongst which are Dengue, Coronaviruses, and pandemic Influenza, as well as [ii] serious intracellular bacterial infectious diseases.

Emergex has a growing proprietary pipeline of innovative CD8+ T cell Adaptive Vaccine and booster vaccine candidates that have the potential to deliver rapid, broad (mutation-agnostic) and long-lasting immunity to reduce serious illness associated with infectious disease. Emergex has a number of Phase I clinical trials underway, of which the most advanced programmes in development are [i] Dengue (which may also be disease-modifying for other members of the *Flaviviridae* virus family, such as Zika and Yellow Fever) and [ii] Coronaviruses. Other programmes in development include vaccine candidates for universal (pandemic) Influenza, Chikungunya, and a booster vaccine for Yellow Fever.

Emergex's T cell Adaptive Vaccines candidates combine two proprietary technologies, [i] an empirically determined library of pathogen-derived protein fragments expressed on the surface of pathogen-infected cells (forming the MHC Class I expression “ligandome” library), and [ii] a passivated gold nanoparticle carrier system designed to deliver the synthetic peptides to the skin-resident immune system (in combination with nociception) via microneedles in order to elicit a robust, adaptive CD8+ T cell response. With potential stability at ambient temperatures, the vaccine candidates are intended to reduce the burden and the logistics of vaccine administration.

Find out more online at www.emergexvaccines.com.

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