Emergex Reports Promising Data from Completed Swiss Phase I Trial of *CoronaTcP*™, T Cell-Priming Immune Set-Point Candidate for Betacoronaviruses

- First-in-human intradermal administration of *CoronaTcP*™ was generally well-tolerated
- Evidence for generation of virus-specific effector and memory CD8+ T cells
- Data reinforce findings from trial of *DengueTcP*, Emergex's product candidate for Dengue, further supporting the company's T cell-based approach to protection against RNA viruses

ABINGDON, United Kingdom, 19 July 2023 – Emergex Vaccines Holding Limited ('Emergex', or the 'Company') a clinical-stage biotechnology company addressing major global infectious diseases through the development of fully synthetic T cell-priming immune set-point candidates, today announced the successful completion of naNO-COVID, a Phase I clinical trial in Switzerland investigating the safety and reactogenicity of *CoronaTcP*™[1] in healthy volunteers. *CoronaTcP* is Emergex's multi-target T cell-priming set-point product, designed to be broadly effective against disease caused by Betacoronaviruses, including SARS-CoV-1, as well as known and emerging variants of SARS-CoV-2, which pose significant epidemic or pandemic risk.

Assessment of primary outcome measures of the trial indicate that *CoronaTcP* showed a favourable safety profile, with no treatment-related serious adverse events observed. The majority (88%) of adverse events were mild, with the most common being injection-site pain. There was no systematic difference between groups that received high or low dose *CoronaTcP,* in terms of overall safety or reactogenicity.

In secondary immunogenicity analyses, the assessment of baseline levels of SARS-CoV-2-specific anti-nucleoprotein antibodies indicated most participants had experienced previous SARS-CoV-2 infection. A number of participants seroconverted during the trial (as a consequence of exposure to SARS-CoV-2) but had mild symptoms, confirming that *CoronaTcP* does not worsen an acute episode of COVID-19. Cellular analyses demonstrated that *CoronaTcP* (two doses administered at Day 0 and 21) was able to activate virus-specific CD8+ T cells, with a significant increase in frequencies of *CoronaTcP*-specific CD8+ CD137+ CD69+ cells following *in vitro* antigenic stimulation in both low and high dose *CoronaTcP* groups at Day 35 post-treatment. Significant changes were also observed for several virus-specific CD8+ memory subsets. Further studies with a larger number of participants are warranted for full assessment of T cell responses, including whether they are the consequence of a prime or a boost, and their correlation with protection.

Overall findings from the first-in-human clinical trials of Emergex's T cell-priming immune set-point candidates against Dengue and Betacoronavirus diseases (naNO-DENGUE and naNO-COVID, respectively) have demonstrated a favorable safety profile. Immunogenicity assessments provide an initial proof of concept that products developed from Emergex's therapeutic platform can successfully induce virus-specific T cell responses. Such results favour the further development of the Dengue and Betacoronavirus candidates in larger clinical trials. Overall, Phase I trial data validate Emergex's T cell-based approach to protection against RNA viruses and confirm the platform's potential using this innovative technology, supporting investigation of other T cell-priming immune set-point candidates from the same platform.

[1] Trademark application submitted

Professor Thomas Rademacher, Co-Founder and Chief Executive Officer, Emergex, said: *"The positive data from both clinical trials – naNO-DENGUE and naNO-COVID - represent an important landmark for Emergex. Demonstrating that our platform has an acceptable safety profile and successfully mobilises specific T cells that may elicit broad and long-term immune memory, validates our approach. By improving T cell-based immunity, we can enhance any previous immune status. We are delighted that this first assessment of a treatment against infectious diseases for clinical use, based solely on a T cell response, was successful.*"

The naNO-COVID Trial

The naNO-COVID trial (NCT05113862) was a Phase I double-blind, randomized, base particle-controlled, single centre study designed to evaluate the safety and reactogenicity of two intradermal injections of an anti-Betacoronavirus candidate, *CoronaTcP*, at two different dosages. Conducted at the clinical investigation unit of the CHUV (Centre Hospitalier Universitaire Vaudois)-UNIL (University of Lausanne) in Switzerland, the study enrolled 26 healthy adult volunteers previously vaccinated against SARS-CoV-2. Participants were randomized to receive one of the following treatments: low-dose *CoronaTcP* (n=10), high-dose *CoronaTcP* (n=10), low-dose base nanoparticle comparator (n=3), or high-dose base nanoparticle comparator (n=3) (low and high-dose *CoronaTcP* being 2.5 nmol or 7.5 nmol total peptide, respectively, and the comparator being the construct base particle without peptides but with equivalent gold content). Each participant received an intradermal injection of the assigned treatment on Day 0 and on Day 21 using a microneedle device and was followed up for six months.

naNO-COVID was the second stage of a two-stage clinical trial of Emergex's T cell priming platform technology, initiated upon the favourable outcome of an interim analysis of safety data from the first stage, naNO-DENGUE.

About Emergex

Emergex is a clinical-stage, privately-held biotechnology company, headquartered in Abingdon, UK, with an operating subsidiary in Doylestown, Pennsylvania, USA. The company is pioneering the development of 100% synthetic, T cell-priming immune set-point therapeutic candidates that harness and direct the body's natural T cell immune response to destroy and to clear pathogen-infected cells, using cytopathic or non-cytopathic mechanisms, in order to provide protection against some of the world's most urgent health threats. Emergex's first indications being pursued are against infectious diseases: [i] viral infectious diseases, amongst which are Betacoronavirus, Dengue Fever and Universal Influenza A (including pandemic influenza) candidates, as well as [ii] intra-cellular bacterial infectious disease, such as tularemia caused by *Francisella tularensis*. In the near future, other disease applications will follow.
Find out more online at www.emergexvaccines.com.

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