



Emergex Announces MHRA Approval of MIA (IMP) Manufacturing and Import Authorisation License

Abingdon, United Kingdom, 18 June 2024 – Emergex Vaccines Holding Limited ('Emergex', or the 'Company'), a clinical-stage biotechnology company addressing major global infectious diseases through the development of synthetic T cell-priming vaccine candidates, today announced that Emergex has received its Manufacturing and Import Authorisation (MIA) Investigational Medicinal Product (IMP) license from the UK's Medicines and Healthcare Products Regulatory Agency (MHRA) to advance its novel T cell-priming vaccine candidates into clinical production. This will provide cGMP grade vaccine Drug Substance to support Emergex's clinical trial pipeline.

Emergex's MIA (IMP) license and cGMP accreditation, issued on 16 April 2024 [MIA (IMP) 57419] follows a rigorous multi-phase regulatory audit inspection of its GMP Quality Systems, Facilities, and Manufacturing Areas, conducted in September 2023 and March 2024.

Laszlo Fekete, Quality Director at Emergex, commented: *"We are thrilled to announce the GMP certification of our in-house facilities, a critical milestone that allows us to confidently proceed with production of our novel T cell-priming vaccine candidates into clinical use. The infectious disease solutions we are developing aim to address significant unmet medical needs, offering the potential to provide coverage for billions of individuals at risk for dengue and pandemic influenza, among other urgent global health challenges. The MIA (IMP) license grants us the privilege and responsibility to manufacture clinical-grade products to protect these huge at-risk populations."*

Laurens Rademacher, Chief Technology Officer at Emergex added: *"For Emergex, this is a milestone we have been working towards since its formation in 2016. Over the years, we have been dedicated to building the necessary infrastructure and establishing key collaborations in high-impact countries around the world. This has included developing innovative technologies such as the Stericube, outsourcing manufacturing in order to most efficiently scale our production capabilities, and engaging in technology transfer strategies to enhance the global reach and impact of our vaccine candidates to where they are needed most. Notably, our strategic ties with entities in Brazil and Saudi Arabia have been crucial in advancing our joint goals with potential to expand access in diverse markets."*

The MHRA is an executive agency of the UK Department of Health and Social Care, which is responsible for ensuring that medicines and medical devices properly work and are acceptably safe. MHRA licensing is globally recognized for requiring the highest standards of safety, quality and effectiveness for any vaccine. The receipt of the MIA (IMP) license makes Emergex the only dedicated gold nanoparticle T cell vaccine cGMP facility in the world.

Emergex's innovative T cell-based vaccines are unique in that they are 100% synthetic in composition, shelf stable for over 3 months at ambient temperatures, and designed to provide long-term and mutation-agnostic coverage against existing and emerging strains of viruses of the same virus family. Designed for delivery via novel microneedle technology, their scalable design and ease of administration facilitates manufacture in bulk, which is particularly crucial during the emergence of pandemics. Furthermore, their design offers improved access to remote and under-resourced regions of the world.

About Emergex

Emergex is a clinical-stage, privately held biotechnology company, headquartered in Abingdon, UK, with an operating subsidiary in Doylestown, Pennsylvania and a GMP manufacturing facility in Fremont, CA, USA. The Company is pioneering the development of 100% synthetic T cell-priming vaccine candidates designed to mimic 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 protect against some of the world's most urgent health threats. The candidates are also specifically designed for administration using novel micro-needles via skin immunisation into the epidermal layer, intended to reduce the burden and logistics associated with conventional preventative measures. Emergex's first indications pursued are against infectious diseases: [i] viral infectious diseases, amongst which are Betacoronaviruses, Dengue Fever and Pandemic Influenza candidates, as well as [ii] intra-cellular bacterial infectious disease, such as tularemia caused by *Francisella tularensis*. Emergex has a growing proprietary pipeline of innovative candidates with potential to deliver rapid, broad (strain and variant agnostic) and long-lasting prevention to reduce serious illness associated with infectious diseases.

Find out more online at www.emergexvaccines.com.
Visit our [LinkedIn page](#) or [Twitter \(X\) account](#) for updates.

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