Successful Transfer of New Drug Application (NDA), Acknowledged by U.S. FDA, from Former Zosano Pharma to Emergex for Investigational Microneedle-Based Drug Delivery Patch

- *Earlier this year, Emergex submitted a notification to the FDA regarding the transfer of ownership of Zosano Pharma's* Microneedle Array Patch (**MAP**) epidermal drug delivery system *to Emergex itself following its acquisition of the operating assets of Zosano, which has been acknowledged by the FDA with the update reflected in its records.*

- *Emergex requested a 12-month extension to the submitted NDA to work toward potential marketing authorization of Zosano's microneedle-based drug delivery patch originally intended to deliver zolmitriptan™ for the treatment of migraines, which will also be repurposed for the delivery of Emergex's T cell-priming candidates. The FDA has acknowledged the extension request.*

Abingdon, Oxon, UK, 18 December 2023 – Emergex Vaccines Holding Limited ('Emergex', or the 'Company'), a clinical-stage biotechnology company addressing major global infectious diseases through the development of T cell-priming, immune set-point drug candidates, today announced that the Company has transferred ownership, as of May 2023, of the existing U.S. Food and Drug Administration (FDA) New Drug Application (NDA) of the investigational MAP originally intended for the epidermal delivery of *zolmitriptan*[1] (also known as M207) for the treatment of migraine attacks in adults. This transfer from the former California-based Zosano Pharma Corporation (Fremont, CA) follows the acquisition of Zosano operating assets by Emergex. Additionally, Emergex has notified the FDA of its request for a 12-month extension of the NDA.

On October 12, 2022, Emergex announced its acquisition of Zosano assets, including intellectual property, license agreements, and manufacturing equipment, as well as Zosano's proprietary MAP epidermal drug delivery system.

Emergex had previously performed proof-of-concept studies with Zosano MAP technology-based microneedle patches coated with Emergex T cell-priming immune set-point candidates, observing favourable results regarding ease-of-use and shelf-life characteristics. The acquisition provided Emergex with innovative technology, among other assets, and optimised manufacturing capabilities that can be deployed for, and integrated with, the development roadmap of Emergex's T cell-priming candidates. In April 2023, Emergex notified the FDA of that acquisition, as a full NDA package which had previously been filed with the FDA by Zosano.

Emergex also notified the FDA of an extension of Zosano's submission of epidermal migraine treatment patch NDA for potential marketing authorization. The extension will allow Emergex to continue manufacturing the epidermal delivery patch with its own pipeline of T cell-priming candidates.

Laurens Rademacher, Chief Technology Officer at Emergex, commented: *"The successful transfer of the NDA marks an important milestone in our goal to lead a new generation of treatments for acute viral infections. We look forward to expanding upon the promise of this MAP technology and are confident that its combination with our T cell-priming candidates will further advance Emergex's core mission to combat viral threats around the world. We now have a highly sophisticated vaccine platform paired with a pragmatic delivery tool, which we believe makes a recipe for success."*

About Epidermal Delivery and MAP Technology

Microneedle array patch (MAP) technology facilitates the use of coated microneedles for epidermal delivery of Emergex immunotherapy candidates to treat acute viral diseases. The novel technology has previously been validated with Emergex products in proof-of-concept studies. The use of MAP technology is intended to overcome the limitations imposed on supply chain logistics by traditional vaccine approaches, which require colder temperatures during both shipping and manufacture and greatly limit global accessibility. The technology also takes advantage of the high levels of antigen-presenting cells present in the skin to induce a stronger immune response while using smaller quantities of antigens. Collectively, the novel drug delivery strategy is intended to provide an effective delivery tool with limited reliance on costly and complex supply chain logistics.

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 immune set-point drug 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 preventive and treatment measures. Emergex's first indications pursued are against infectious diseases: [i] viral infectious diseases, amongst which are Betacoronaviruses, Dengue Fever and Universal Influenza (including 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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[1] Zolmitriptan is an active drug used to treat acute migraine headaches in adults, currently available under various brand names, such as *Zomig*®, among others.