EU Grant Supports Universal Influenza Vaccine Clinical Development

Leiden, The Netherlands – 5 June 2023 – A consortium of eight academic and industry partners is advancing the development of a universal influenza vaccine with a €7.6 million grant from the European Union. Through its FLUniversal programme, the consortium will conduct clinical trials of DeltaFLU, a rapid-acting universal influenza vaccine for intranasal administration. FLUniversal also will seek to elucidate molecular and immunological mechanisms of protection, and identify potential new correlates of protection using data from clinical trials and preclinical models. The partners will develop a novel controlled human infection model (CHIM) and influenza challenge strain which they will use to evaluate protective efficacy of DeltaFLU in a clinical challenge study.

Ed Schmidt, PhD, Project Manager at consortium member Leiden University Medical Center (LUMC) remarked, "Influenza is a major public health problem globally. A universal influenza vaccine that provides protection against all seasonal influenza strains and emerging strains with pandemic potential is an urgent goal. The FLUniversal consortium unites world-leading experts with the tools and knowledge to develop a novel universal influenza vaccine that already has surmounted key hurdles of novel vaccines: demonstration of safety and robust immunogenicity in humans and manufacturability. Our synergistic combination of preclinical models, a CHIM to produce results similar to wild-type infection, clinical samples, and integrated complex immunological analyses form a unique platform to identify molecular signatures of protection and reduce the timeline and risks involved in clinical development."

DeltaFLU universal influenza vaccine, developed and owned by FLUniversal partner Vivaldi Biosciences, is based on influenza virus strains genetically modified to eliminate the NS1 gene. This genetic modification results in the ability of DeltaFLU to rapidly induce interferon and broadly cross-neutralising antibodies in the nasal passages, generating protection at the point of entry of influenza viruses, and establishing tissue-resident memory T cells for protection against repeat infection. The self-adjuvanting effect of interferon enhances T and B cell activity for a broadly protective systemic immune response. Deletion of NS1 also makes DeltaFLU safe because the genetically modified strains are unable to produce viral progeny and are not shed by vaccine recipients. Vivaldi has demonstrated safety and broad immunogenicity of DeltaFLU vaccine strains in clinical trials, and achieved proof of concept for universal protection against influenza A and B strains in animal models.

LUMC and the Centre for Human Drug Research are responsible for the clinical studies in the FLUniversal programme: a Phase 1 study of safety and immunogenicity of DeltaFLU, a clinical study to characterise the novel influenza challenge strain and validate the CHIM, and a clinical challenge study of DeltaFLU in healthy adult volunteers to demonstrate protective efficacy. Vivaldi is responsible for GMP manufacture of the DeltaFLU vaccines and novel challenge strain using its high-yield Vero cell production system. The Medicines and Healthcare Products Regulatory Agency of the UK, participating in FLUniversal as an associate partner, is responsible for the isolation, selection and characterisation of the novel influenza virus challenge strain.

MediTox, a GLP-certified contract research organisation with extensive expertise in nonclinical pharmacology and toxicology studies, will conduct the preclinical studies of DeltaFLU. Studies in the ferret model will include evaluations of safety, immunogenicity and challenge-protection. MediTox will further study DeltaFLU in the Syrian golden hamster model to identify immune fingerprints that correlate with protection against transmission of influenza virus from infected to immunised animals. Statens Serum Institut, an infectious disease research institute under the Danish Ministry of Health, will

use state of the art techniques to evaluate samples from the preclinical and clinical studies, including cellular analyses of samples from the blood and nasal mucosa, to identify correlates of protection. VisMederi, a leader in validating immunological assay services, with unique competence in GCLP-accredited qualified sample analysis, will carry out integrated complex immunological assays for the identification of molecular signatures of protection. Zafiro Business Solutions, a consulting and advisory organisation specialising in EU programmes, serves as the FLUniversal programme coordinator, with responsibility for project management and compliance with ethics requirements.

FLUniversal (Project Name: Intranasal, rapid-acting vaccine for all seasonal and pandemic influenza viruses) is funded under the European Union's Horizon Europe Framework Programme (HORIZON).

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