

CureVac Announces Start of Combined Phase 1/2 Study in Avian Influenza (H₅N₁); Development in Collaboration with GSK

Phase 1 part of combined Phase 1/2 study initiated as part of pandemic preparedness against highly pathogenic avian influenza (H5N1) virus, considered to be potential future pandemic threat. Study will assess monovalent vaccine candidate, encoding an influenza A H5-antigen using proprietary second-generation mRNA backbone. Avian influenza is latest program progressing to clinical trials under broad infectious disease collaboration agreement with GSK.

CureVac N.V. (Nasdaq: CVAC) ("CureVac"), a global biopharmaceutical company developing a new class of transformative medicines based on messenger ribonucleic acid ("mRNA"), today announced the start of the Phase 1 part of a combined Phase 1/2 study of an investigational influenza A (H5N1) pre-pandemic vaccine candidate developed in collaboration with GSK. The H5N1 avian influenza virus is considered a potential future pandemic threat, known to sporadically cross species from its original bird host to other animal hosts and humans. The monovalent vaccine candidate is based on CureVac's proprietary second-generation mRNA backbone and encodes an influenza A H5-antigen.

"The highly pathogenic avian influenza virus is frequently cited as one of the viruses with high pandemic potential, with cases of animal-to-human transmission of the H5N1 strain already documented. Leveraging our clinically validated mRNA-technology platform and second-generation mRNA backbone, we aim to provide an effective countermeasure to the pandemic threat of potential human-to-human transmission", said Dr. Myriam Mendila, Chief Development Officer of CureVac. "This clinical milestone, in collaboration with GSK, expands the application of our mRNA technology into an additional indication in infectious diseases and addresses the need to be prepared for potential future pandemics."

The combined Phase 1/2 study will evaluate the safety, reactogenicity and immunogenicity of an investigational influenza A (H5N1) pre-pandemic vaccine candidate in healthy younger adults aged 18 to 64 and healthy older adults aged 65 to 85. In the initial Phase 1 dose-escalation part of the study, up to five dose levels will be assessed compared to a placebo control. The study will be conducted in the United States.

The broad CureVac-GSK infectious disease collaboration was first announced in July 2020. It focuses on applying CureVac's mRNA-technology to the development of new products for infectious disease targets.

Press release

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Source: CureVac SE

Further information

- ▶ CureVac
- ▶ GlaxoSmithKline (GSK)