

GYLDEN PHARMA ANNOUNCES ENROLMENT COMPLETE FOR PHASE 1 TRIAL OF GOLD NANOPARTICLE-BASED COVID-19 VACCINE CANDIDATE UNDER U.S. GOVERNMENT'S PROJECT NEXTGEN INITIATIVE

U.S. Clinical Testing Of Gylden Pharma's Synthetic T Cell Vaccine Platform Under NIH/
NIAID-Sponsored Study Achieves Enrolment Milestone

ABINGDON, United Kingdom, 16 July 2026 – Gylden Pharma Ltd, a clinical-stage biotechnology company developing innovative precision intradermal therapeutics, announced today that enrolment is now complete for a Phase 1 clinical trial (NCT number NCT07183709) of its COVID-19 vaccine candidate, funded and implemented by the U.S. National Institutes of Health's (NIH's) National Institute of Allergy and Infectious Diseases (NIAID). The trial is part of the U.S. Department of Health and Human Services' Project NextGen, a programme evaluating next-generation platforms for vaccines and therapeutics through public-private partnerships.

Project NextGen aims to identify vaccines and therapeutics with enhanced breadth of protection against disease variants, improved durability, and greater ability to prevent infection and transmission – addressing key limitations of first-generation COVID-19 vaccines as the virus continues to evolve. Gylden Pharma's gold nanoparticle-based platform is designed to offer cross-reactive protection against variants of viruses of the same family and to extend the duration of the vaccine's immune protection.

Conducted by a NIAID-funded network of clinical trial sites, the study aims to evaluate the safety, reactogenicity, and immunogenicity of Gylden's synthetic nanoparticle-based, T cell-priming peptide vaccine candidate against betacoronaviruses (including SARS-CoV-2), when administered as a booster dose in healthy adults. Between February and April 2026, the study enrolled a total of 60 subjects, across three dose cohorts, with all subjects receiving active treatment. Participants will be followed for six months. The Last Subject Last Visit (LSLV) for the study will occur in October 2026. There has been no immediate safety concern to-date.

"We're honoured to be included in the Project NextGen programme" said Professor Thomas Rademacher, Scientific Founder of Gylden. "We're pleased that enrolment has been completed for this first U.S. clinical trial for one of our vaccines and are grateful to the investigators and study participants. We look forward to demonstrating the safety of this technology and what it can achieve to support broad and robust, long-term immunity against infectious diseases including COVID-19."

HOW THE TECHNOLOGY DIFFERS

Currently licensed COVID-19 vaccines prime the immune system to recognize specific viral proteins (e.g. membrane-associated spike proteins) as foreign, prompting the production of antibodies tailored to particular strains. These approaches can become less effective as spike proteins mutate, requiring updated vaccine formulations and multiple administrations in order to provide protection.

Gylden Pharma's approach delivers synthetic viral peptides attached to very small gold clusters for uptake by antigen presenting cells (APCs). These APCs can then activate T cells which target infected cells for destruction. Importantly, T cells can recognize variations of the virus which provides broader and more durable protection. Gylden Pharma's focus is to reduce the onset and severity of disease by increasing virus-specific T cell immunity to enable killing of infected cells at the time of infection. Because the technology is fully synthetic, it reduces the safety concerns associated with live-attenuated or weakened viruses used in some traditional vaccines.

The company has previously completed safety trials in Europe, with Phase 1 clinical trials of its betacoronavirus (NCT05113862) and dengue virus (NCT04935801) constructs conducted in Switzerland, establishing a foundation of clinical data supporting the platform's safety profile. Regulatory approval has also recently been received to conduct a first-in-human study in the UK of a chikungunya vaccine candidate based on the same platform.

REGULATORY MILESTONE AND NEXT STEPS

The inclusion in Project NextGen represents the first active Investigational New Drug (IND) with the U.S. Food and Drug Administration (FDA) for Gylden's synthetic nanoparticle-based, T cell-priming peptide vaccine candidate – a critical regulatory milestone that enables clinical testing in the United States and opens potential pathways for future commercial development and partnerships.

Results from the US Phase 1 trial are expected to be released by the IND holder (NIAID Division of Microbiology and Infectious Diseases [DMID]) within a year of LSLV. Positive results would support advancement to later-stage trials and potential expansion of the platform to other infectious disease targets.

ABOUT GYLDEN PHARMA LTD

Gylden Pharma Ltd is a clinical-stage biotechnology company developing innovative precision intradermal therapeutics. Based in Abingdon, United Kingdom, the company's gold nanoparticle platform is designed to provide broad, durable immune protection through innovative delivery mechanisms suitable for global deployment. For more information, please visit www.gyldenpharma.com or contact:

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