GYLDEN PHARMA RECEIVES REGULATORY APPROVAL FOR A PHASE I CLINICAL TRIAL OF A NOVEL SYNTHETIC T CELL-PRIMING VACCINE CANDIDATE AGAINST CHIKUNGUNYA VIRUS

- UK regulatory authority has granted approval for a Phase 1 clinical trial of Gylden's chikungunya vaccine candidate
- The Phase 1 clinical trial will evaluate the safety of the vaccine candidate and provide an initial assessment of the T cell immune response in healthy volunteers

Abingdon, United Kingdom, 16 July 2026 – Gylden Pharma Ltd, a clinical-stage biotechnology company developing innovative precision intradermal therapeutics, today announces that it has received approval from the UK Medicines and Healthcare products Regulatory Agency (MHRA) and local Research Ethic Committee to conduct a Phase 1, dose-escalation, randomized, single-blind, placebo-controlled trial of its chikungunya (CHIKV) vaccine candidate.

The Phase 1 trial will be a single site study and has been designed to enrol 40 healthy adults across four dose escalating cohorts. Subjects will receive two doses of either active or placebo treatment, 42 days apart. Safety, reactogenicity and immunogenicity will be assessed over a one-year follow-up period.

The CHIKV construct is the latest Gylden vaccine candidate to be advanced into clinical stage development and uses a gold nanoparticle-peptide based T cell-priming platform, designed to deliver broad and long-lasting immunity by priming the body's T cells to rapidly clear infected cells. With the potential to suppress duration of viraemia, the vaccine candidates could also influence epidemiologic control of CHIKV. Preclinical studies of the CHIKV vaccine candidate have provided evidence of safety and immunogenicity in animal models, supporting advancement of the investigational vaccine towards clinical evaluation.

Using the T cell-priming platform, Gylden has successfully completed Phase 1 trials in Switzerland of dengue and betacoronavirus (SARS-CoV-1 and SARS-CoV-2) vaccine candidates, which were shown to be safe and capable of inducing desired T cell effector and memory responses. A further Phase 1 safety trial of the COVID-19 vaccine candidate (NCT07183709), part of the U.S. Department of Health and Human Services' Project NextGen, has successfully completed dosing of all participants.

Professor Thomas Rademacher, Scientific Founder of Gylden commented: "*CHIKV has become a global health concern, and we believe that there is a real need for a vaccine that induces virus-specific CD8+ T cell immunity that can reduce the potential for vaccine-induced antibody-*

mediated enhancement of disease. We are pleased to have progressed our T cell-priming vaccine candidate through its first regulatory submission and approval, and look forward to advancing the vaccine into clinical testing in both naïve and endemic populations."

About Chikungunya

Chikungunya is an RNA virus that belongs to the *alphavirus* genus of the *Togaviridae* family of viruses. It is transmitted through the bite of an infected mosquito and can cause epidemics of infectious disease. The illness is characterized by fever, rash, debilitating joint stiffness and arthritis, which can endure for months to years following infection. CHIKV is present in many parts of the world, especially in tropical and sub-tropical regions of Africa, Asia, and the Americas, where *Aedes aegypti* or *Aedes albopictus* (tiger) mosquitoes – the primary carriers of the virus – are found. The virus has also spread to new areas (occasionally causing outbreaks), such as Europe and North America, through infected travelers and influenced by climate change expanding the geographic distribution of Aedes mosquitoes. In 2025, a resurgence of CHIKV disease was noted in a number of countries, including some that had not reported substantial case numbers in recent years.[1] This year, as of March 2026, there have been >32,000 CHIKVD cases and nine associated deaths reported worldwide.[2]

There is no specific anti-viral treatment for CHIKV infections. Two vaccines have received regulatory approvals and/or have been recommended for use in populations at risk in several countries. Unfortunately, the vaccines are not yet widely available nor in widespread use due to safety concerns. There is a need for new CHIKV vaccines.

ABOUT GYLDEN PHARMA LTD

Gylden Pharma Ltd is a clinical-stage biotechnology 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, visit www.gyldenpharma.com or contact:

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