

Stablepharma Doses First Patient in Pivotal Phase 2b Trial After Positive Clinical Results

The pivotal 160-patient study represents the final clinical step towards commercialisation of SPVX02, Stablepharma's fridge-free, freeze-resistant Td vaccine.

LONDON, ENG, UNITED KINGDOM, October 7, 2026 /EINPresswire.com/ -- Following publication of positive Phase 1 results in [The Lancet/ eClinicalMedicine](#), the pivotal 160-patient study represents the final clinical step towards commercialisation of SPVX02, [Stablepharma's](#) fridge-free, freeze-resistant tetanus-diphtheria vaccine.

Stablepharma Ltd, the biotechnology company developing fridge-free vaccines and pharmaceuticals, today announced that the first participant has been dosed in a Phase 2b clinical trial of SPVX02, its thermostable tetanus-diphtheria (Td) booster vaccine developed using the company's proprietary StablevaX™ technology.



Ozgur Tuncer, CEO & Executive Director

The trial follows the publication of Stablepharma's positive Phase 1 clinical trial results in eClinicalMedicine, part of The Lancet family of journals, and marks the final clinical development step towards commercialising a vaccine designed to eliminate dependence on refrigerated storage and distribution.

The randomised, single-blind, non-inferiority study conducted in the UK, will enrol 160 healthy adults and is expected to demonstrate that SPVX02 generates post-boost immune responses that are non-inferior to Tetadif®, the licensed WHO-prequalified tetanus-diphtheria originator vaccine. The study will also evaluate the safety and tolerability of SPVX02.

Stablepharma's first-in-human Phase 1 results were published in eClinicalMedicine (The Lancet). The publication reported that SPVX02 demonstrated a strong safety profile and generated

immune responses comparable to licensed Td vaccines. It provided the first published human evidence that an aluminium-adjuvanted vaccine can be reformulated into a fridge-free, freeze-resistant product without any impact on safety or loss of immune performance.

SPVX02 is a lyophilised reformulation of Tetadif and is designed to remain stable at temperatures up to 40°C and resist freezing. Ongoing real-time stability studies have demonstrated potency retention for at least 6 months at 40°C and for 24 months at 30°C, supporting Stablepharma's goal of eliminating dependence on costly and complex cold-chain infrastructure.

Özgür Tuncer, Chief Executive Officer of Stablepharma, said:

"The publication of our Phase 1 data in eClinicalMedicine provided independent validation of the science underpinning SPVX02.

The launch of this Phase 2b study is the final critical step on the pathway towards commercialisation.

"Our ambition, however, extends far beyond a single vaccine. We believe StablevaX™ can help pharmaceutical partners develop fridge-free versions of vaccines, biologics and other temperature-sensitive medicines to strengthen healthcare supply chains worldwide.

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Our ambition goes beyond a single vaccine. StablevaX™ can help pharmaceutical partners develop fridge-free versions of vaccines and other refrigerated medicines to strengthen healthcare worldwide.”

Özgür Tuncer CEO & Executive Director



Dr Karen O'Hanlon, Chief Operating Officer

Dr Karen O'Hanlon, Chief Operating Officer of Stablepharma, added:

"For many vaccines and medicines, cold-chain storage has long been accepted as unavoidable. This study is designed to generate the clinical evidence needed to advance SPVX02 towards commercialisation while demonstrating the broader potential of the platform to transform how temperature-sensitive medicines are stored and

distributed worldwide."

Chief Investigator for the study, said:

"This study is designed to provide robust clinical evidence on the immunogenicity, safety and tolerability of SPVX02 compared with its originator, licensed vaccine, Tetadif. The results will

help determine whether this approach to vaccine thermostabilisation can offer a real, practical alternative product to conventional refrigerated vaccines.”

Eligible participants in the Phase 2b study will have previously received a primary tetanus and diphtheria vaccination and will be randomised 1:1 to receive a single dose of either SPVX02 or Tetadif. Immune responses and safety outcomes will be assessed for 28 days post-dose.

SPVX02 forms part of Stablepharma’s broader strategy to apply their StablevaX™ technology across a range of vaccines, biologics and temperature-sensitive pharmaceutical products, including anti-infectives, oncology products and other medicines that currently depend on refrigeration throughout storage and distribution.



Stablepharma's Fridge-free Tetanus Diphtheria Vaccine - SPVX02

About the Phase 2b study

- Study design: Randomised, single-blind, non-inferiority
- Participants: 160 healthy adults
- Comparator: Tetadif®, a licensed WHO-prequalified Td vaccine
- Primary objective: To assess non-inferior post-booster immune responses and evaluate safety and tolerability
- Trial site: Manchester, UK
- First participant dosing: 6 October 2026
- IRAS ID: 1014057
- Study protocol: SPL-SPVX02-02

About SPVX02

SPVX02 is a thermostable, lyophilised tetanus-diphtheria booster vaccine developed using Stablepharma’s proprietary StablevaX™ technology. Unlike conventional vaccines requiring storage at 2–8°C, SPVX02 is designed to remain stable at temperatures up to 30°C and resist freezing, potentially reducing or eliminating the need for refrigerated storage and distribution.

About Stablepharma

Stablepharma is a UK biotechnology company developing thermostable, fridge-free formulations of vaccines and pharmaceuticals. Through its proprietary StablevaX™ platform, the company aims to address global challenges associated with cold-chain dependence, product wastage, supply-chain resilience, cost and environmental impact.

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