The Lancet's eClinicalMedicine Publishes Phase I Data for SPVX02, a Fridge-free Td Vaccine Stable for 24 Months at 30°C

Stablepharma announce Phase 1 clinical trial results for SPVX02, a thermostable reformulation of a licensed Td vaccine, published in the eClinicalMedicine

Stablepharma's Fridge-free Tetanus Diphtheria Vaccine - SPVX02

LONDON, ENG, UNITED KINGDOM, August 5, 2026 /EINPresswire.com/ -- Stablepharma Limited today announced that the Phase 1 clinical trial results for SPVX02, its room temperature stable reformulation of a licensed tetanus–diphtheria (Td) vaccine, have now been peer reviewed and published in the eClinicalMedicine (part of The Lancet family of journals). The publication marks a major milestone for thermostable vaccine innovation and provides independently validated evidence supporting the safety, stability and immunogenicity of the SPVX02 vaccine candidate.

Developed using Stablepharma's proprietary StablevaX™ technology, SPVX02 demonstrated safety and immune responses profiles comparable to licensed Td vaccines, providing the first in-human evidence that an aluminium adjuvanted vaccine can be reformulated into a fridge free, freeze resistant product without loss of efficacy.

SPVX02 is a lyophilised, room temperature stable version of Tetadif, a WHO prequalified Td vaccine manufactured by BB NCIPD in Bulgaria. Unlike conventional Td vaccines, SPVX02 remains fully stable at ambient temperatures and is resistant to freezing. Ongoing real time stability studies show that SPVX02 retains potency for at least 24 months at 30°C, with analysis continuing toward a 48 month target. This represents a meaningful advancement in reducing reliance on the costly and unreliable global cold chain while improving vaccine access.

Clinical Trial Overview: "The multicentre, blinded, randomised Phase 1 trial enrolled 60 healthy adults who had been vaccinated against tetanus and diphtheria more than ten years prior," said

Dr Karen O'Hanlon, Chief Operating Officer, Stablepharma. "Across all treatment groups, no vaccine related serious adverse events were observed, and reactogenicity was predominantly mild to moderate in severity. By day 28, 100% of participants receiving SPVX02 achieved protective antitoxin levels for both tetanus and diphtheria, mirroring the immunogenicity of licensed comparator vaccines. We are delighted with these robust clinical trial results."


Özgür Tuncer CEO & Executive Director

Professor Saul Faust, Professor of Paediatric Immunology and Infectious Diseases at the University of Southampton and Director of the NIHR Clinical Research Facility in Southampton, who led the Phase 1 study, said:
"Keeping vaccines cold from the factory to the patient is one of the biggest challenges facing immunisation programmes worldwide. Our study suggests that this vaccine can remain safe and effective without refrigeration. If larger studies confirm these findings, this technology could help transform the way vaccines are stored and delivered around the world."

> These findings strengthen the scientific and global health case for a new generation of fridge-free vaccine and pharmaceuticals, particularly in regions where cold chain limitations hinder access."
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> *Özgür Tuncer CEO & Executive Director*

The publication of the SPVX02 Phase 1 findings highlights the broader global health implications of thermostable vaccines. Cold chain failures continue to contribute to substantial vaccine wastage worldwide, and the healthcare sector accounts for 4.4% of total global carbon emissions, equivalent to two gigatons of CO□.* A room temperature stable vaccine and pharmaceuticals could help national immunisation programmes strengthen supply resilience, reduce waste, and meaningfully reduce the environmental burden associated with refrigeration, distribution and storage.

"This peer reviewed validation represents a pivotal moment for our StablevaX™ platform and the future of thermostable vaccines," said Özgür Tuncer, CEO & Executive Director, Stablepharma. "These findings strengthen the scientific and global health case for a new generation of fridge free vaccines, particularly in regions where cold chain limitations hinder equitable access."

Stablepharma has commenced participant recruitment for a randomised, single-blind, non-inferiority Phase 2b clinical trial, which will be conducted at the Medicines Evaluation Unit (MEU) in Manchester. This clinical trial will include 160 healthy adults aged 18–60 years.


Dr Karen O'Hanlon, Chief Operating Officer

“We see a clear opportunity to continue our collaborations with forward thinking vaccine manufacturers,” added Tuncer. “SPVX02 is a clear demonstration of the potential we have identified for fridge-free formulations – our StablevaX™ platform can play a transformative role across multiple therapeutic categories, such as oncology and anti-infectives.”

About Stablepharma

Stablepharma is a UK and Spain based biotech developing thermostable, fridge free formulations that address global challenges in distribution, storage, wastage, and CO emissions associated with temperature sensitive medicines. Its proprietary StablevaX™ technology enables approved vaccines and pharmaceuticals to be reformulated into products that remain stable without refrigeration, without compromising efficacy. Stablepharma is committed to advancing global health equity, reducing waste, and supporting more resilient, sustainable healthcare systems.
* Source: Intelsius – “The Environmental Impact of the Pharmaceutical Cold Chain”

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Laura Murphy
Stablepharma Ltd
+44 7789 850837
lmurphy@stablepharma.com
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