Virometix Announces Completion of Enrollment in Phase I Trial of V-212 — a Fully Synthetic, Serotype-Independent Vaccine Candidate Against Streptococcus Pneumoniae

Schlieren, Switzerland – 29 September 2025 – **Virometix AG**, a Swiss clinical-stage biotechnology company pioneering fully synthetic vaccines, today announced that it has successfully completed enrollment in the Phase I clinical trial of **V-212**, a peptide-based, serotype-independent vaccine candidate targeting Streptococcus pneumoniae infections.

"Completing enrollment in this Phase I trial marks a significant milestone for V-212," said Anna Sumeray, CEO of Virometix. "This fully synthetic, serotype-independent vaccine candidate is designed to advance our mission of delivering scalable, safe, and broad-spectrum protection against pneumococcal disease, while addressing the current limitations of existing PCV approaches. Through our collaboration with CEVAC, we are well-positioned to deliver high-quality Phase I data, with topline results anticipated in the first quarter of 2026."

Prof. Isabel Leroux-Roels, Principal Investigator at CEVAC, added:
"We are proud to collaborate with Virometix on this first-in-human study of V-212. Pneumococcal infections remain a major global health challenge, underscoring the urgent need for next-generation vaccines with broader and more durable protection. V-212's fully synthetic, serotype-independent approach is highly innovative, and we look forward to advancing the clinical evaluation of this important candidate."

About Virometix and the V-212 Program
Virometix develops structure-based, fully synthetic nanoparticle vaccines designed to elicit targeted, robust, and durable immune responses. Its proprietary Synthetic Virus-Like Particle (SVLP) platform employs conformational synthetic peptide mimetics displayed on self-assembling lipopeptidic nanoparticles that include built-in adjuvant elements, including T-helper epitopes and Toll-like receptor (TLR) ligands—eliminating dependence on biological components and simplifying manufacturing.

V-212, the lead pneumococcal vaccine candidate, is specifically engineered as a serotype-independent, peptide-based immunogen. Multiple conserved antigenic epitopes from key Streptococcus pneumoniae surface proteins are synthesized and conjugated to SVLP nanoparticles, aiming to induce broad immunity across diverse serotypes—addressing the limitations of current conjugate vaccines.

Preclinical studies have demonstrated robust, long-lasting immunogenicity in mouse and rabbit models. V-212 prevented lethal sepsis in a serotype 3 challenge, inhibited bacterial dissemination into blood, and reduced pulmonary burden. It also conferred protection against serotype 8 infections. Moreover, antisera elicited by V-212 recognized multiple pneumococcal serotypes, including non-PCV-13 types, underscoring its serotype-independent potential.

Phase I Trial Design and Enrollment Highlights

- **Study ID**: NCT06975319 (VMX-SPN-212-001)
- **Design**: A randomized, double-blind, placebo-controlled, first-in-human, Phase I trial in healthy adult volunteers.
- **Participants**: A total of 60 healthy subjects aged 18–45 years have been enrolled.

- **Collaboration**: The trial is being conducted in collaboration with CEVAC (Centre for Vaccinology) at Ghent University Hospital, a leading European clinical trial unit with extensive expertise in vaccine development.
- **Dosing Regimen**: Subjects receive three intramuscular injections of either V-212 or placebo, across low, medium, and high dose groups to assess safety, tolerability, and immunogenicity.
- **Primary Objective**: Evaluate safety and tolerability across dose levels.
- **Secondary Objective**: Assess immunogenicity to identify an optimal dose for subsequent studies.
- **Next Milestone**: Topline safety and immunogenicity data are expected in Q1 2026.

About Virometix

Virometix AG is a privately held Swiss biotechnology company developing a new generation of fully synthetic vaccines to generate targeted and protective immune responses against infectious diseases and cancer. There is a considerable medical need for vaccines to combat infectious as well as a number of chronic human diseases, including cancer. Rational molecular design, chemical synthesis and Virometix' proprietary “Synthetic Virus-Like Particle” platform technology allow for the rapid production and optimization of vaccine candidates with the potential to demonstrate superior properties in terms of safety, efficacy, ease and cost of manufacturing and stability. Learn more at www.virometix.com

Forward-Looking Statements
This release contains forward-looking statements regarding the clinical development of V-212. Trial outcomes, timelines, and future steps involve inherent risks and uncertainties.

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