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## **Cyto Pulse, the Karolinska Institute and the Swedish Institute for Infectious Disease Control Receive Phase I Clinical Trial Approval from the Swedish Medical Products Agency to Evaluate an HIV Vaccine in Healthy Volunteers**

GLEN BURNIE, Md.--([BUSINESS WIRE](#))--Cyto Pulse Sciences, a leading producer of electric field based, intradermal DNA Vaccine delivery systems, today announced approval from the Swedish Medical Products Agency to conduct a phase I clinical trial evaluating an HIV/DNA vaccine in collaboration with the Karolinska Institutet (KI) and the Swedish Institute for Infectious Disease Control (SMI). The vaccine will be delivered to healthy volunteers by ZetaJet®, a needle-free injection system (Bioject Medical Technologies Inc.) in combination with the intradermal electroporation system, Derma Vax™ (Cyto Pulse). The study will be sponsored by SMI and conducted at Södersjukhuset, KI, by Principal Investigator Bo Hejdeman, M.D., Ph.D. The multivalent HIV vaccine was developed jointly by SMI and KI.

The combination of intradermal injection by ZetaJet® and electroporation by Derma Vax™ is thought to potentiate and broaden the response of the vaccine. Clinical Investigator and Professor of Dermatovenerology, Eric Sandström, M.D., Ph.D. says: "Our studies have shown that low dose (1mg) intradermal Bioject DNA injections induce stronger and broader priming to HIV antigens than 'standard' (4mg) intramuscular priming. Dermal electroporation of HIV/DNA may further increase this effect."

**"We are optimistic the treatment will be effective and therefore have signed a letter of intent to participate in a follow-up Phase II trial in Tanzania and Mozambique"**

Britta Wahren, M.D., Ph.D., Professor in Clinical Virology at KI/SMI and responsible for the HIV vaccine constructs, says: "We expect that this type of delivery for genetic vaccines will strongly enhance the effect of the immunogen. It is likely that the combined delivery of vaccine genes by both the ZetaJet and electroporation can lead to a lower effective dose of vaccine DNA."

The Derma Vax™ delivery system is designed to be safe, effective and highly tolerable for the patient. "We are optimistic the treatment will be effective and therefore have signed a letter of intent to participate in a follow-up Phase II trial in Tanzania and Mozambique," said Derin Walters, Cyto Pulse CEO.

### **About Cyto Pulse Sciences**

Cyto Pulse Sciences, Inc. is a biomedical device and treatment development company creating innovative technology to produce and deliver new therapeutics for cancer (immunotherapy), infectious diseases (prophylaxis therapy), and genetic defects (gene therapy). Cyto Pulse technology is used in a wide range of fields including monoclonal antibody discovery, polynucleotide vaccine production, and delivery of polynucleotide (DNA/RNA) vaccines. Additional information is available at <http://www.cytopulse.com>.

### **About Karolinska Institutet**

Karolinska Institutet is Sweden's largest centre for medical training and research. It is also one of Europe's leading medical universities and among the Nordic region's foremost life sciences innovation centers. Additional information is available at <http://ki.se>.

### **Contacts**

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