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Cyto Pulse, the Karolinska Hospital/Institutet and SMI Receive Approval from the Swedish Medical Products Agency to Start a Clinical Trial Evaluating a CEA-based Vaccine in Patients with Colorectal Cancer.

GLEN BURNIE, Md.--([BUSINESS WIRE](#))--Cyto Pulse Sciences, a leading producer of electric field based, intradermal DNA Vaccine delivery systems, today announced approval by the Swedish regulatory authorities to begin a Phase I/II study of DNA vaccination in patients with colorectal cancer. The trial will investigate the safety of a DNA vaccine delivered by the Derma Vax™ intradermal electroporation system. The vaccine, which encodes Carcinoembryonic Antigen (CEA), was developed jointly by the Swedish Institute for Infectious Disease Control (SMI)/Karolinska Institutet (KI) and Cyto Pulse.

Britta Wahren, M.D., Ph.D., Professor in Clinical Virology at KI/SMI and responsible for the CEA vaccine construct, says "we expect this type of gene delivery to be more immunogenic than previous deliveries. When competing against cancer, one way is to redirect the patient's immune response to eradicate many or all tumor cells in the body." The trial is sponsored by Prof. Håkan Mellstedt, M.D., Ph.D., and will be conducted at the Department of Oncology/Pathology at the Karolinska University Hospital/Institutet. Principal Investigator Maria Liljefors M.D., Ph.D., and Prof. Håkan Mellstedt say "we have worked with CEA vaccination for very long time and we want to improve the strategy. We are very excited about this technology approach which may strongly enhance the immune response."

"We are pleased to announce this trial as part of ongoing efforts to validate Cyto Pulse technology in the clinic," said Derin Walters, Cyto Pulse CEO. "Our partners at Karolinska have been instrumental in advancing Derma Vax™ as the leading DNA vaccine delivery platform. Derma Vax™ is designed to be safe, well tolerated, and effective, and we are hopeful the treatment will prove this to be the case."

About Karolinska Hospital/ Institutet

Karolinska University Hospital is one of Scandinavia's premier health facilities. Together with the world-respected Karolinska Institutet (KI), they lead in medical break-throughs in Sweden. KI is one of Europe's largest medical universities. It is also Sweden's largest centre for medical training and research.

About Cyto Pulse Sciences

Cyto Pulse Sciences, Inc. is a biomedical device and treatment development company commercializing innovative technology to produce and deliver therapeutics for cancer treatments (immunotherapy), protection against infectious diseases (prophylaxis therapy), and correcting 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 on Cyto Pulse is available at the company's website, <http://www.cytopulse.com>.

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