Genetic Immunity Developing Next Generation of DNA Vaccine Platform for HIV Therapy, Various Cancers

Genetic Immunity, a US clinical stage biotechnology company, is developing DermaVir, a nanomedicine lead product candidate for the treatment of HIV and other chronic diseases. The company is looking for financial partners that can help offset the costs associated with the Breakthrough Therapy Designation submission to the FDA.

(PRWEB) October 31, 2017 -- Genetic Immunity, a US clinical stage biotechnology company, is developing DermaVir, a nanomedicine lead product candidate for the treatment of HIV.

“DermaVir is the next generation of plasmid DNA-based vaccine for the treatment of chronic diseases,” said Viktor Rozsnay, CEO of Genetic Immunity. “Based on FDA classification, it is a combination of a new biologic product DermaVir and our new medical device DermaPrep.”

DermaVir contains a novel plasmid DNA that encodes most HIV genes, administered topically using the DermaPrep medical device.

‘Proof of concept’ for the immunological and antiviral activities of DermaVir was demonstrated in infected macaques, some of them with advanced stages of AIDS. Analysis of data derived from these animal trials showed that repeated DermaVir administration resulted in a cumulative strengthening of the antiviral immune response without adding significant toxicities or adverse effects.

Plasmid DNA-based vaccines have been proven safe, but poorly immunogenic, in human subjects. Genetic Immunity has developed several technologies to improve the immunogenicity of DNA-encoded antigens, including:
- Antigeneering of plasmid DNA to safely and authentically express most of the antigens of HIV or other pathogens.
- The formulation of plasmid DNA to a pathogen-like nanoparticle called NanoComp. These nanoparticles target professional antigen-presenting cells, such as Langerhans cells and dendritic cells.
- A targeted transdermal delivery device called DermaPrep. It has been shown that topical DermaPrep administration results in antigen expression in the lymph.

“Following successful preclinical studies, we completed a Phase I, Phase I/II, conducted by the IDS Clinical Trials Group and funded by the National Institutes of Health in the USA, and a Phase II trial,” continued Rozsnay.

“In these studies, we successfully demonstrated that DermaVir immunization induces new, HIV-specific memory T-cells that correlated to the amount of nanomedicine the subject received. Our data to date supports proof of concept, the relationship between DermaVir-induced antiviral immune responses and clinical benefit.”

Based on these results, Genetic Immunity believes that DermaVir would bring significant benefit to HIV patients worldwide.

“As our first step towards a marketed product we applied for Breakthrough Therapy Designation with the FDA, and received regulatory feedback and a request for additional information. To supply this information, we are looking for financial partners that can help offset the costs associated with the submission,” concluded

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Rozsnyay.

According to the WHO, there were 36.7 million people living with HIV/AIDS, and one million deaths of HIV-related illnesses, in 2016 worldwide.

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