Immunitor Publishes Placebo-Controlled, Phase II Trial of Its Therapeutic AIDS Vaccine

*Immunitor USA Inc., today announced that its licensed vaccine candidate V-1 Immunitor (V1) has shown promising results in Phase II, placebo-controlled, clinical trial involving 47 HIV-infected individuals. The study was published in the special December issue of the Journal of Clinical Virology Â– the official journal of The Pan American Society for Clinical Virology and The European Society for Clinical Virology.*

College Park, MD (PRWEB) December 8, 2004 -- Immunitor USA Inc., today announced that its licensed vaccine candidate V-1 Immunitor (V1) has shown promising results in Phase II, placebo-controlled, clinical trial involving 47 HIV-infected individuals. The study was published in the special December issue of the Journal of Clinical Virology Â– the official journal of The Pan American Society for Clinical Virology and The European Society for Clinical Virology. The abstract of the paper is now available on PubMed - the website of the National Library of Medicine http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=pubmed&dopt=Abstract&list_uids=15567095

At the end of 6-month study volunteers who were treated with V1 had statistically significant increase in CD4-positive T-cell numbers (p=0.01). However, in the placebo group that has received sham pills, the changes in T-cell counts failed to reach the significance threshold (p=0.33). The clinical potential of V1 was further supported by an elevation in CD4/CD8 ratio among V1 recipients and decline in CD4/CD8 ratio in patients on placebo. The average weight gain among patients on V1 was 1.8 kg while placebo group lost 0.5 kg. These results indicate that V1 can delay or reverse the HIV disease progression without any concurrent toxicity.

"Our published data supports earlier published, Phase I studies of V1 demonstrating increase in T-lymphocyte numbers, decrease in viral load, body weight gain, and improved survival of end-stage AIDS patients,Â” said Vichai Jirathitikal, the inventor of the oral vaccine technology. "The study provides additional evidence that this type of vaccine might ultimately be effective as a safe and effective treatment for AIDS and potentially other autoimmune diseases as well."

" The very first clinical study of V1 was published in 2002. In just two years we were able to achieve the major milestone in drug development process, which is the pivotal Phase II trial. We have accomplished this despite major and obvious difficulties and we are looking forward to confirm such results in Phase III clinical trial," said Dr. Aldar S. Bourinbaier, CEO.

Due to toxicity and drug resistance problems associated with conventional antiviral chemotherapy, the therapeutic use of AIDS vaccines is receiving increased attention in the medical community. There has been considerable experience with this type of approach, with several dozen clinical trials reported over the last twenty years. While the immune response appeared to change as a result of therapeutic vaccination in most, if not all studies, there was no demonstrable clinical benefit. Despite this setback many clinical studies of various therapeutic vaccines are in progress, which may eventually help to identify an effective strategy.

V-1 Immunitor is an experimental AIDS vaccine made as an ordinary pill and comprises heat- and chemically-inactivated viral antigens derived from the pooled blood of HIV-positive donors. V1, which is taken orally on a
daily basis, is thought to function by modulating the mucosal immune response. This innovative method of vaccine administration places the emphasis on oral tolerization of alloantigens delivered through the gut. V1 is the first therapeutic AIDS vaccine that has shown the clinical improvement in AIDS patients when administered orally.

###
Contact Information
Aldar Bourinbaiar
Immunitor
http://www.immunitor.com
301 4749369

Online Web 2.0 Version
You can read the online version of this press release here.