EVRY, France, Dec. 1, 2013 /PRNewswire/ -- InnaVirVax SA today announced the initiation of a Phase 2 clinical trial assessing the therapeutic properties of the VAC-3S vaccine when combined with standard antiretroviral therapy (ART) in the course of HIV-1 infection.

"On this World AIDS Day, the advancement of VAC-3S into this Phase 2 study is an important step forward. We recognize we have much work to do towards the goal of durable treatments for patients and their families affected by HIV, and our company is rising to meet this challenge," said Shahin Gharakhanian, MD, InnaVirVax Chief Medical Officer.

The primary objective of the Phase 2 study is to assess antibody response to the VAC-3S vaccine. VAC-3S has been constructed to induce a humoral immune response against a highly conserved region of the gp41envelope protein of the HIV-1 known as 3S. A complement to ART, VAC-3S is a therapeutic vaccine candidate that acts on the immune system via CD4+ T-cells, a key factor responsible for progression of the disease during HIV-1 infection. Notably, data available from human cohort studies and/or non-human primate models indicate anti-3S antibodies are associated to an increase in CD4+ T cells and a decrease of HIV viral reservoirs as well as HIV inflammatory biomarkers. VAC-3S is composed of three distinct but covalently linked parts so as to optimize production of an immune response. Secondary objectives include overall general and local tolerance as well as clinical safety, comprehensive evaluation of the immunological endpoints, inflammatory biomarkers, HIV reservoir, as well as identifying the vaccine's immunogenic characteristics.

A phase I dose escalation study of VAC-3S previously performed in 33 patients living with HIV whose CD4 T-lymphocyte levels were higher than 200 mm^3 and who were on ART, demonstrated safety and provided data for dose selection.

About the VAC-3S Phase 2 Study

The Phase 2 study is a randomized, double-blind, placebo-controlled study among HIV-1 infected adults with viral load less than or equal to 50 copies/mm^3 treated with ART, whose CD4+ T-cell count at screening is between 200 and 500 cells/mm^3. A total of 90 patients will be studied in France, Germany and Spain. Three VAC-3S doses will be compared. First a 3 months base vaccination will be performed; then 3-maintenance injections in two of three dosage groups and a 6-month follow-up period.

"We've assembled a blue ribbon International US / EU Clinical Advisory Board to guide us and highly experienced group of clinical investigators and stellar network of reference laboratories to conduct assessments. Coordinating principal investigators for the three countries are Professors Christine Katlama, Paris, France, Juergen Rockstroh in Bonn, Germany and Jose Gatell in Barcelona, Spain (*co-chair of 2013 AIDS vaccine conference*). InnaVirVax thus marks this World AIDS Day with a very innovative program to meaningfully address this challenging infection," said Joel Crouzet, CEO of InnaVirVax.

Additional information about the study will be found at clinicaltrials.gov .

About InnaVirVax

Based in the Genopole hub in Evry, InnaVirVax is a biopharmaceutical company researching and developing therapeutic and diagnostic solutions for diseases linked to the immune system through its research on immune deregulations, the company has developed a portfolio of

innovative products for use in HIV and against chronic inflammatory diseases. The most advanced project is a therapeutic vaccine (VAC-3S) for the treatment of HIV infections, is in Phase I/IIa clinical development. The safety or efficacy of VAC-3S has not been established. Founded in 2008, support for the company is from the French Ministry for Higher Education and Research, BPI France, the National Research Agency (ANR), the Ilede-France Centre for Innovation, and investors including CapDecisif, G1J Ilede-France, Pradeyrol Developpement, Fa Diese and the Fonds Regional de Co-Investissement Ile-de-France.

For more information, visit our newly launched website: www.innavirvax.fr

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