PRESS RELEASE

For immediate circulation

InnaVirVax: the Phase I/IIa clinical study of its VAC-3S immunotherapeutic vaccine in the treatment of HIV infection has achieved its primary endpoint

Interim results of the phase I/IIa clinical study revealed a good safety and tolerability profile for the VAC-3S immunotherapeutic vaccine, which was the primary endpoint of the study performed in two AP-HP reference clinical centers in Paris, France, at Pitié Salpêtrière and Cochin Hospitals.

Evry, 29 November 2012 – InnaVirVax, a biopharmaceutical company specialized in research and development on therapeutic and diagnostic solutions for diseases linked to immune dysregulation, has just announced successful completion of the first clinical development phase for VAC-3S immunotherapy in the treatment of HIV infections.

A phase I/IIa dose escalation study was performed in 24 patients living with HIV whose CD4 T-lymphocyte levels were higher than 200/mm^3 and who were under antiretroviral therapy [ART].

The treatment was administered in 3 injections at 4-week intervals. The primary endpoint of this study was to assess the safety and tolerability of VAC-3S, four weeks after the third injection. Secondary endpoints included an evaluation of the immune response, the long-term safety of the treatment and the monitoring of different biological markers of infection (including viral load and the CD4 T-lymphocyte count). The study was carried out under double-blinded conditions in two AP-HP *(Paris Public Hospitals System*) academic reference clinical centers at Hôpital de la Pitié Salpêtrière and Hôpital Cochin.

The results showed that VAC-3S was well tolerated, thus meeting the primary endpoint of the study. Full results of this study will be presented at an international medical conference.

Professor Christine Katlama, in the Infectious and Tropical Diseases Department at Hôpital de la Pitié Salpêtrière and principal investigator for the study, stated: *"These results are important insofar as the primary study endpoint has been achieved. A treatment regimen consisting of three injections of VAC-3S was thus well tolerated. This is a key stage in the clinical development of this immunotherapy, which will supplement the antiretroviral therapies that are currently available."* **Professor Odile Launay, Coordinating Physician at the Cochin-Pasteur Vaccinology Clinical Investigation Center at Hôpital Cochin, and joint investigator for the study, added:** *"Observation of the safety of VAC-3S after three injections is very encouraging in terms of the future development prospects for this immunotherapy".*

Dr Shahin Gharakhanian, acting Chief Medical Officer of InnaVirVax who is based in the Cambridge Innovation Center (Cambridge, Massachusetts, USA), went on: *"We are looking forward to analyzing these results in detail in terms of the full set of endpoints.*

We are also actively preparing the next stage, which will involve submission of an application for a Phase II clinical study that takes account of the regulatory requirements for our type of product. We are also in discussion with US and European experts, and thus are working closely with clinicians in major centers.

Joël Crouzet, CEO of InnaVirVax concluded: "*These clinical data obtained with the candidate immunotherapy VAC-3S are encouraging. The promising findings we are revealing today confirm the validity of our strategy, which aims to protect a patient's immune system. VAC-3S may therefore constitute an innovation for HIV patients by preserving their immune system".*

About InnaVirVax:

Based in the Genopole® incubator hub in Evry, InnaVirVax is a biopharmaceutical company specialized in research and development on therapeutic and diagnostic solutions for diseases linked to immune dysregulation. Through its research on immune dysregulations, the company has developed a portfolio of innovative products for use in HIV and oncology. The most advanced project concerns an immunotherapy (VAC-3S) for the treatment of Human Immunodeficiency Virus (HIV) infections. This is currently in its Phase I/IIa clinical phase. Set up in 2008, the company has since received support from the French Ministry for Higher Education and Research, OSEO, the National Research Agency (ANR), the Ile-de-France Centre for Innovation, and investors which include CapDecisif, G1J Ile-de-France, Pradeyrol Développement, Fa Dièse and the *Fonds Régional de Co-Investissement Ile-de-France*. For more information, go to: www.innavirvax.fr.

Contacts:

InnaVirVax
Joël CROUZET – CEO
Tel.: +33 1 80 85 60 83
jc@innavirvax.fr

Milestones – Press Relations
Bruno ARABIAN
Tel.: +33 1 75 44 87 40 / +33 6 87 88 47 26
barabian@milestones.fr