AGENCE FRANCAISE DE SECURITE SANITAIRE DES PRODUITS DE SANTE

Presse release

January 15th, 2003

Severe Combinated Immuno-Deficiency

By the end of August 2002 a serious adverse event was notified in a patient included in the first gene therapy clinical trial, aimed at correcting the X-linked severe combined immuno-deficiency (X-SCID), conducted by professors Marina Cavazzana-Calvo and Alain Fischer at Necker-Enfants Malades hospital in Paris, France (see Afssaps press release, October 3rd 2002).

Upon notification of this event, the clinical trial was put on hold by the sponsor, in agreement with the French Medical products Safety agency (Afssaps). Since then no other patients have been included in the trial and the first eight patients, who had received the gene therapy product, have been subject to an intensive clinical and biological follow-up.

Very recently, the principal investigators have detected, in a second patient, an abnormal and monoclonal proliferation of T-lymphocytes, characteristics of which are very close to the case reported in the first young patient.

As for the first case, the patient is receiving a chemotherapy; a satisfactory clinical response has been so far obtained for the two patients.

Further investigations, have been initiated in an attempt to better explain the mechanism of the adverse event, so as to develop methods able to prevent this risk.

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