anRS Agence nationale de recherches sur le sida et les hépatites virales
French national agency for research on AIDS and viral hepatitis

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A l'attention de Monsieur Jean MARIMBERT
directeur de l'AFSSAPS

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Mister the Director,

We hereby inform you by this present letter of the premature termination of the trial ANRS HB 05. A randomized, double blind, multicenter study evaluating efficacy and safety of Clevudine monotherapy versus Tenofovir monotherapy versus combination therapy of Clevudine and Tenofovir for 96 weeks in HBeAg negative patients with chronic hepatitis B, naïve to anti-VHB therapy.

Indeed, after the recent publication in 2009 in Hepatology, presenting the first cases of myopathies occured under treatment by Clévudine in a therapeutic trial, and recent undesirable event reports, the Pharmasset laboratory has sought to better document the frequency and conditions of the occurrence of myopathies in the patients under treatment in Korea where Clévudine has a marketing authorisation.

The outcome of these investigations has revealed the occurrence of myopathies more frequent and more severe than those recently reported in therapeutic trials, some of which are associated with mitochondrial toxicity which could be one of the causes of myopathies found.

Despite promising clinical results for the treatment of hepatitis B, this latest information calls into question the balance of benefit/risk of the Clévudine therefore no longer in favour of a benefit for the patients.

The laboratory Pharmasset, according with the FDA , has announced on the 20th of April 2009, the decision to stop the developement of Clévudine.

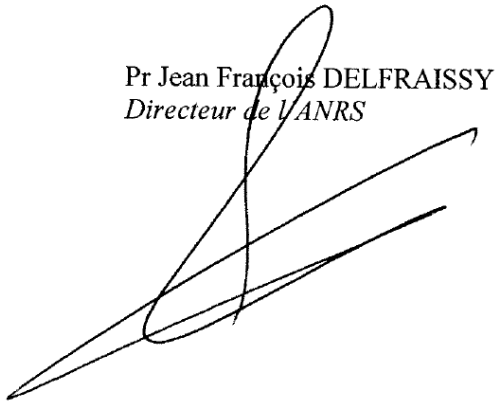
As a consequence, the trail of ANRS HB 05 was definitvely stopped.

The pre inclusions and inclusions of the trial ANRS HB 05 were stopped on the 22nd of April 2009, a letter was sent to all the investigators on the 24th of April 2009.
Two patients were included (after blind lifting, 1 patient under Clévudine, 1 patient under Ténofovir)

To this day, these patients are well and will undergo this week,a fully clinical examination. The investigators indicated their intention to treat these patients by Ténofovir as part of the monitoring of their pathology.

We remain at your disposal for any further information, please receive, Mr the Director, the assurance of our respectful greetings.

Pr Jean François DELFRAISSY
Directeur de l'ANRS



Cc : Mme Chantal BELORGEY-BISMUT
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