federal agency for medicines and health products

Research and Development

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Your letter from	Your reference	Our reference	Annex	Date
		FAGG/R&D/LSA		

Onderwerp
Titre de l'objet
Subject

Goedkeuring van een klinische proef op 18/10/2012
Approbation d'un essai clinique le 18/10/2012
Authorisation of a clinical trial dated 18/10/2012

Dossier OGM B/BE/12/BVW1: A multi-center, randomized, double blind, placebo-controlled Phase I/II trial to compare the safety, tolerability and immunogenicity of the therapeutic THV01 vaccination at 5x10E6 TU, 5x10E7 TU or 5x10E8 TU doses to placebo in HIV-1 clade B infected patients under highly active antiretroviral therapy

EudraCT: 2012-006260-52

Chère Madame, Cher Monsieur,

Conformément à l'article 12 de la Loi du 7 mai 2004 relative aux expérimentations sur la personne humaine, j'ai décidé d'autoriser l'essai clinique ci-dessus mentionné.

Cependant, un suivi doit être apporté aux points mentionnés en annexe.

Salutations sincères,

Pour la Vice-Première Ministre et Ministre des Affaires sociales et de la Santé publique

Geachte Mevrouw, Geachte Heer,

In overeenstemming met artikel 12 van de wet van 7 mei 2004 inzake experimenten op de menselijke persoon, heb ik besloten de hierboven vermelde proef goed te keuren.

Niettemin moet er gevolg gegeven worden aan de opmerkingen vermeld in bijlage.

Met de meeste hoogachting,

Voor de Vice-Eerste Minister en Minister van Sociale Zaken en Volksgezondheid

Dr. Greet Musch

Unofficial translation

In accordance with article 12 of the Law of 7 May 2004 concerning experiments on the human person, I have decided to authorise the above mentioned clinical trial. However, the points as mentioned in annex are to be followed up.

Annex

There are no grounds for non-acceptance arising from the non-clinical assessment of the investigational medicinal product. Therefore, we have no objections against the start of the Clinical Trial.

However, the sponsor is recommended to take into consideration the following points (i.e. recommendations) given in annex during further development of the product. They may be readdressed at the time of assessment of future applications related to this investigational medicinal product.

1. The justification of the Applicant on the absence of tumorigenicity studies, based on clearance of transfected cells cannot be accepted. For further development of the product, integration studies will have to be performed and depending on the results of these in vitro studies, tumorigenicity studies might be required.

2. It is agreed with the Applicant that the positive signals observed at day 56 in the GLP biodistribution study are very weak. It is also agreed that the preferential intronic integration of lentiviral vectors and the fact that the promoter used does not have an enhancer activity lowers the risks of insertional mutagenesis. However, this risk cannot be ruled out and should be addressed. This was also the conclusion of CHMP and SAWP during the scientific advice.