

Sponsor's protocol code number : GFT505-207-2

Title: A Pilot study to evaluate the Efficacy and Safety of GFT505 orally administered once daily (30 mg) for 28 days in atherogenic dyslipidaemic patients with abdominal obesity. A double blind, placebo-controlled and randomized study.

EudraCT N°: 2007-004337-41

Global end of trial date: 07 March 2008

Sponsor: Genfit

The clinical study was prematurely ended by the Sponsor on March 7, 2008.

The recruitment in France had begun on January 19th 2008, and 35 atherogenic dyslipidaemic patients with abdominal obesity had been selected but none were randomised when the Sponsor made its decision to prematurely stop the study.

This decision was made following the availability of the GFT505-207-1 study results (EudraCT N° : 2007-003237-16 (<https://www.clinicaltrialsregister.eu/ctr-search/trial/2007-003237-16/results>) in patients with Frederickson Type IIb Dyslipidemia (Mixed Hyperlipidemia). The Sponsor considered the dose of 30 mg/day of GFT505 and the study design was non-optimum to reach the objectives of the clinical study. No safety concerns motivated the decision to prematurely end the clinical study.

As no GFT505 treatment had been administered to any patient, the Sponsor decided that the data that could have been collected during this study would not be neither analyzed, nor entered or proceeded so no Clinical Study Report have been issued.