113 Phase II study in young CF adults with the recombinant acid lipase MERISPASE®

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This study involving the recombinant acid lipase MERISPASE® [1,2] was conducted in 24 CF adult patients during the six last months of 2007. The aim was to confirm the safety and the efficacy of the r-lipase added with low doses of CREON®.

This was a monocenter, single blind study according to cross-over and parallel group protocols. Three sessions were designed: Session 1: all patients received low doses of pancreatic extract; Session 2: patients treated with 3 different doses of lipase compared with a fourth group taking 84,000 U of PE; Session 3: was the add-on phase since all patients received low doses CREON® whereas the three MERISPASE® group pursued. The full results will be given orally, but:

1. The safety was excellent with no severe side effects.
2. The tolerance was also good and all 24 adults completed the study.
3. MERISPASE® alone had as previously observed a dramatic effect on CFA when this criteria was low at the beginning of the study.
4. However, MERISPASE® alone was unable to fully correct CFA. Its addition to low doses of CREON® gave in contrast a similar result (without any differences in the clinical signs of local tolerance) than when the patient was taking high doses of pancreatic extract.

The results permitted us to design the phase III.

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Reference(s)

[1] Hubert D. Copenhagen 2006.
[2] Lenoir G. Denver 2006.