Prematurely ended statement

EudraCT number	2013-001869-16
Full title of the study	A randomized, multi-center, parallel group, double-blind, placebo-controlled study to assess the efficacy and safety of Oscillococcinum® in the treatment of symptoms of influenza-like illness (ILI)
Sponsor	Boiron Laboratoires
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Product	Oscillococcinum®
Date of the early termination	19 May 2014
Statement on discontinuation of the study	The results of the 1st Interim Analysis were discussed with the Sponsor and the Data Monitoring Committee, and it was decided to stop the study for futility. Superiority of Oscillococcinum® versus placebo regarding the primary endpoint - time to absence of systemic flu-like symptoms - and the co-primary endpoint - time to absence of systemic AND alleviation of respiratory flu-like symptoms - could not be demonstrated for the total Full Set Analysis (FAS) population. Enrolment was stratified according to the total symptom score to achieve a more balanced symptom load. In the FAS population, in patients with a total symptom score between 2 and 8, there was a statistical trend for superiority of Oscillococcinum® versus placebo regarding the primary endpoint (p=0.056) and the co-primary endpoint (p=0.0688). Further results from Per Protocol population (PP) showing statistically significant advantages of Oscillococcinum® versus placebo for primary (p=0.0359) and co-primary endpoints (p=0.0365) confirm this trend. Overall, Oscillococcinum® was safe and well tolerated: the safety profile was very similar for the two groups. Occurrence of adverse events was balanced between both treatment groups (20 patients (11.4%) in the Oscillococcinum® group and 19 patients (10.8%) in the placebo group).

Isabelle Chanel
Director of R&D and scientific and medical affairs

Signature