Branded Pharmaceutical Products R&D

April 28, 2015

Sponsor's statement concerning unavailability of paediatric clinical trial results at this time point

Concerned study:
EudraCT 2012-005510-20
Protocol C10953/1100 entitled: *"A Randomized, Open-Label Study to Characterize the Pharmacokinetics, Pharmacodynamics, and Safety of Single and Multiple Doses of Armodafinil (50, 100, and 150 mg) in Children and Adolescents with Excessive Sleepiness Associated with Narcolepsy"*

Approach of posting this statement in the EudraCT database has been endorsed by EMA and the content thereof confirmed with FIMEA, the only EU Competent Authority concerned with this study.

No paediatric study results are available at this time point due to the following reasons:

- A local premature end of trial notification for Finland has been submitted to Fimea according to local law due to lack of recruitment on 6 March 2014 while this study is still ongoing in the US. Fimea has entered the information that no patients were enrolled for the trial in Finland in the secure EudraCT- database, not visible in the public EudraCT domain.
- It was agreed with Fimea that once the global study will be completed, a global end of trial notification will be submitted
- Within 6 months of the LPLV date to be included in the global end of trial notification, the clinical trial results will be posted in the EudraCT database

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