EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

20 December 2012
EMA/PRAC/821161/2012

PRAC List of questions

To be addressed by the marketing authorisation holder for Tredaptive, Pelzont and Trevaclyn

Procedures under Article 20(8) of Regulation (EC) No 726/2004, following procedural steps of Article 107i

Procedure numbers: Tredaptive EMEA/H/C/889/A-20/0037
Pelzont EMEA/H/C/903/A-20/0038
Trevaclyn EMEA/H/C/897/A-20/0038

INNs: laropiprant and nicotinic acid

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The marketing authorisation holder MAH for Tredaptive, Pelzont and Trevaclyn is requested to:

Question 1

Provide a study report of the HPS2-THRIVE study with all available data including a detailed analysis of:

- mortality outcomes, including time-to-event data
- cardiovascular outcome data,
- adverse events, in particular for the significantly increased gastrointestinal- and intracranial bleeding, new onset diabetes, infections, skin reactions and myopathy.

Please also provide an analysis of the above-mentioned data according to ethnic differences (European, Chinese).

Question 2

Provide the interim results of ongoing studies, if available, and discuss how to proceed with these studies.

Question 3

Provide and discuss a pooled analysis of the clinical studies from the current development program of Tredaptive with regard to the significant increase in serious adverse events seen in HPS2-THRIVE.

Question 4

Submit a detailed benefit-risk analysis of Tredaptive, Pelzont and Trevaclyn taking into account all available data. The benefit-risk analysis should include a discussion on patient populations at special risk, patient populations that might benefit from the drug and patient populations in which the benefit-risk ratio may be positive.