15 September 2016
EMA/693049/2016
Human Medicines Evaluation Division

Assessment report for paediatric studies submitted according to Article 46 of the Regulation (EC) No 1901/2006

Pegasys

peginterferon alfa-2a

Procedure no: EMEA/H/C/000395/P46/053

Note

Assessment report as adopted by the CHMP with all information of a commercially confidential nature deleted.

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1. Introduction

On 07 July 2016, the MAH submitted a completed paediatric study for Pegasys (peginterferon alfa-2a, PEG-IFN), in accordance with Article 46 of Regulation (EC) No1901/2006, as amended.

A short critical expert overview has also been provided.

The MAH is planning to submit a Type II variation with a new indication to update the SmPC with data from the YV25718 study. The variation will be submitted in November 2016 dependent upon the timing of a positive PIP compliance check, currently anticipated in October 2016.

CHMP comment

This report does not present a final assessment of the submitted study results. The submitted clinical study report will be assessed as part of the upcoming new indication variation.

2. Scientific discussion

2.1. Information on the development program

The MAH stated that YV25718 is a stand-alone study.

The YV25718 study is part of the approved Pegasys Paediatric Investigation Plan (EMEA-000298-PIP01-08-M05) for the treatment of Hepatitis B.

2.2. Information on the pharmaceutical formulation used in the study

PEG-IFN (180 µg/mL) was supplied as 2-mL glass vials containing an injectable solution (benzyl alcohol, sodium chloride, sodium acetate trihydrate, acetic acid [glacial], polysorbate 80, and water for injection).

2.3. Clinical aspects

2.3.1. Introduction

The MAH submitted a final report for:

- YV25718 - A Phase IIIb Parallel Group, Open Label Study of Pegylated Interferon alfa-2a Monotherapy (PEG-IFN, Ro 25-8310) Compared to Untreated Control in Children with HBeAg Positive Chronic Hepatitis B in the Immune Active Phase.

2.3.2. Clinical study

Study YV25718

Study YV25718 was a 2:1 randomized, controlled, parallel-group, open-label, multicenter study of PEG-IFN treatment in patients aged 3 to ≤17 years, compared with an untreated control. Patients without advanced fibrosis were randomized 2:1 to PEG-IFN treatment (Group A) or untreated control (Group B), respectively. Patients with advanced fibrosis were assigned to PEG-IFN treatment (Group

C). Patients were dosed using a body surface area (BSA)-category based dosing regimen. This regimen was based on the one approved in Europe for the treatment of pediatric patients with CHC.

3. Rapporteur's overall conclusion and recommendation

Overall conclusion

As the MAH intends to submit a type II variation based on the YV25718 clinical study report, the full review and assessment of the submitted study will be conducted as part of the upcoming new indication variation. There are no safety signals that require regulatory action before the anticipated type II variation.

This assessment report concludes the current procedure.

Recommendation

☒ **Fulfilled:**

No further action required

This study will be fully reviewed in the future new indication variation.

☐ **Not fulfilled:**

Additional clarifications requested

Not applicable.