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Human Medicines Research and Development Support Division

Summary of the evaluation of the proposed paediatric investigation plan

Trifarotene for the treatment of acne

On 18 July 2014, the Paediatric Committee of the European Medicines Agency agreed a Paediatric Investigation Plan* (PIP) for trifarotene for the treatment of acne (EMEA-001492-PIP01-13).

What is trifarotene, and how is it expected to work?

Trifarotene is not authorised anywhere in the world. Studies in adults are currently on-going. This medicine is proposed in adults for the treatment of acne vulgaris.

This medicine is expected to treat acne by altering skin cornification and thereby reducing the blockage and the subsequent inflammation of pores.

What was the proposal from the applicant?

For children, the applicant proposed:

To study the medicine in children from 9 to 17 years old affected by acne, in a paediatric investigation plan*. The future indication proposed for children is: Treatment of acne vulgaris. The plan included a proposal to determine the right dose and to show efficacy and safety of the medicine in clinical studies.

Is there a need to treat children affected by acne?

Taking into account the proposed indication in adults, and the characteristics of the medicine, the Paediatric Committee considered this medicine of potential use for the treatment of acne. This condition occurs also in children and affects in particular adolescents.

What did the Paediatric Committee conclude on the potential use of this medicine in children?

At present, some treatments are available for the treatment of acne in children in the European Union, such as benzoyl peroxide, retinoids and antibiotics. However, current treatments may induce resistance (antibiotics), cause photosensitivity and skin reactions. Therefore, the Committee considered that new data were required to decide whether the use of this medicine will bring a benefit to the children affected by the condition, and to understand any potential risks.

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Because there is a need for more medicines for the treatment of acne in children, and this medicine has a potential interest for children, the Committee considered that clinical studies were necessary.

The Committee considered that studies with children should start and be completed without waiting for all the results of studies in adults.

Studies with children will be done between 2013 and 2016.

What is the content of the Plan after evaluation?

The Paediatric Committee considered that:

- Studies are not necessary in children before puberty because the specific medicinal product does not represent a significant therapeutic benefit over existing treatments.
- It is necessary to show efficacy to treat the disease in children. This will be done in 4 studies comparing the medicine to placebo and active controls.

What happens next?

The applicant has now received the EMA Decision* on this medicine. The Decision itself is necessary for the applicant to request in the future a marketing authorisation* for this medicine in adults and/or in children.

The Decision* on the agreed Paediatric Investigation Plan means that the applicant will perform the studies and trials in the next months or years. In case of difficulties, or a change in current knowledge or availability of new data, the applicant may request changes to the plan at a later stage. This can be done through a modification of the PIP.

The agreed completion of all the studies and trials included in the Paediatric Investigation Plan is October 2016.

The results of the studies conducted in accordance with the agreed Paediatric Investigation Plan will be assessed, and any relevant information will be included in the Product Information (summary of product characteristics, package leaflet). If the medicine proves to be effective and safe to use in children, it can be authorised for paediatric use, with appropriate recommendations on the dose and on necessary precautions. The product information will also describe which adverse effects are expected with the medicine, and wherever possible, how to prevent or reduce these effects.

*Definitions:

Applicant	The pharmaceutical company or person proposing the Paediatric Investigation Plan or requesting the Product-Specific Waiver
Children	All children, from birth to the day of the 18th birthday.
Paediatric investigation plan (PIP)	Set of studies and measures, usually including clinical studies in children, to evaluate the benefits and the risks of the use of a medicine in children, for a given disease or condition. A PIP may include "partial" waivers (for example, for younger children) and/or a deferral (see below).
Waiver	An exemption from conducting studies in children, for a given disease or condition. This can be granted for all children (product-specific waiver), or in specific subsets (partial waiver): for example, in boys or in children below a given age.
Deferral	The possibility to request marketing authorisation for the use of the medicine in adults, before completing one or more of the studies /measures included in a PIP. The Paediatric Committee may grant a deferral to avoid a delay in the availability of the medicine for adults.
Opinion	The result of the evaluation by the Paediatric Committee of the European Medicines Agency. The opinion may grant a product-specific waiver, or agree a PIP.
Decision	The legal act issued by the European Medicines Agency, which puts into effect the Opinion of the Paediatric Committee.
Pharmaceutical form	The physical aspect of the medicine (the form in which it is presented), for example: a tablet, capsule, powder, solution for injection, etc. A medicine can have more than one pharmaceutical form.
Route of administration	How a medicine is given to the patient. For example: for oral use, for intramuscular use, for intravenous use, etc. The same medicine, or the same pharmaceutical form, may be given through more than one route of administration.
Patent	A form of protection of intellectual property rights. If a medicinal product is protected by a patent, the patent holder has the sole right to make, use, and sell the product, for a limited period. In certain circumstances, a patent for a medicinal product may be extended for a variable period by a Supplementary Protection Certificate.
Marketing Authorisation	When a Marketing Authorisation is granted, the pharmaceutical company may start selling the medicine in the relevant country (in the whole European Union, if the procedure was a centralised one).