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Human Medicines Research and Development Support Division

# Public summary of the evaluation of the proposed paediatric investigation plan

## Brodalumab for treatment of psoriasis

On 15 August 2014, the Paediatric Committee of the European Medicines Agency agreed a Paediatric Investigation Plan* (PIP) for brodalumab for the treatment of psoriasis (EMEA-001089-PIP02-13).

### What is brodalumab, and how is it expected to work?

Brodalumab is not authorised in the European Union. Studies in adults are currently on-going. This medicine is proposed in adults for the treatment of moderate to severe psoriasis.

This medicine is a human monoclonal antibody, expected to bind to the interleukin-17 receptor and to prevent this receptor from being activated by interleukin 17 (IL-17).

### What was the proposal from the applicant?

For children, the applicant proposed:

To study the medicine in children from 4 years to 18 years old affected by chronic severe plaque psoriasis, in a paediatric investigation plan*. The future indication proposed for children is: treatment of chronic severe plaque psoriasis. The plan includes the development of a specific pharmaceutical form to be used in children* solution for injection in a prefilled syringe. It also includes 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 psoriasis?

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 psoriasis. This condition occurs also in children.

### 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 psoriasis in children in the European Union, such as etanercept are known to work. Therefore, the Committee considered that new data are

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.

The Committee considered that there is also a need to develop a specific pharmaceutical form* of this medicine, which would allow to use the medicine safely and accurately in young children (solution for injection in a prefilled syringe), and whose composition* must only include components that are known to be safe in children.

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

## What is the content of the Plan after evaluation?

The Paediatric Committee considered that:

- Studies are not necessary in some age groups of children because the specific medicinal product does not represent a significant therapeutic benefit as the needs are already covered.
- A pharmaceutical form* such as a solution for injection in a prefilled syringe was needed. A solution for injection in a prefilled syringe will be developed by the applicant.
- It is necessary to study if the medicine is effective to treat the disease in children. This will be done in 3 studies comparing the medicine to active controls.
- It is necessary to study the potential side effects of the medicine, to prevent them or to reduce the consequences if they occur. The main concern identified by the PDCO is the potential toxicity of the medicine to the immune system.

## 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 is bound to perform the studies and trials with children 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 January 2026.

Trials in the Paediatric Investigation Plan will be listed in the public EU Clinical Trials Register (https://www.clinicaltrialsregister.eu/) as soon as they have been authorised to be started, and their results will have to be listed in the register within 6 months after they have completed.

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:

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| 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). |