EMA/313851/2020

European Medicines Agency decision

P/0239/2020

of 16 June 2020

on the acceptance of a modification of an agreed paediatric investigation plan for anifrolumab (EMEA-001435-PIP02-16-M01) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

Disclaimer

This decision does not constitute entitlement to the rewards and incentives referred to in Title V of Regulation (EC) No 1901/2006.

Only the English text is authentic.

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The European Medicines Agency,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use and amending Regulation (EEC) No. 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004[1],

Having regard to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency[2],

Having regard to the European Medicines Agency's P/0075/2018 issued on 16 March 2018,

Having regard to the application submitted by AstraZeneca AB on 23 March 2020 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a deferral and a waiver,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 29 May 2020, in accordance with Article 22 of Regulation (EC) No 1901/2006,

Having regard to Article 25 of Regulation (EC) No 1901/2006,

Whereas:

(1) The Paediatric Committee of the European Medicines Agency has given an opinion on the acceptance of changes to the agreed paediatric investigation plan.

(2) It is therefore appropriate to adopt a decision on the acceptance of changes to the agreed paediatric investigation plan.

[1] OJ L 378, 27.12.2006, p.1.
[2] OJ L 136, 30.4.2004, p. 1.

Has adopted this decision:

Article 1

Changes to the agreed paediatric investigation plan for anifrolumab, solution for injection, intravenous use, subcutaneous use, are hereby accepted in the scope set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices.

Article 2

This decision is addressed to AstraZeneca AB, Sodertalje, SE-15185 Sodertalje, Sweden.

EMA/PDCO/202983/2020
Amsterdam, 29 May 2020

Opinion of the Paediatric Committee on the acceptance of a modification of an agreed Paediatric Investigation Plan

EMEA-001435-PIP02-16-M01

Scope of the application

Active substance(s):

Anifrolumab

Condition(s):

Treatment of systemic lupus erythematosus

Pharmaceutical form(s):

Solution for injection

Route(s) of administration:

Intravenous use

Subcutaneous use

Name/corporate name of the PIP applicant:

AstraZeneca AB

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, AstraZeneca AB submitted to the European Medicines Agency on 23 March 2020 an application for modification of the agreed paediatric investigation plan with a deferral and a waiver as set out in the European Medicines Agency's decision P/0075/2018 issued on 16 March 2018.

The application for modification proposed changes to the agreed paediatric investigation plan.

The procedure started on 30 April 2020.

Scope of the modification

Some measures and timelines of the Paediatric Investigation Plan have been modified.

Opinion

1. The Paediatric Committee, having assessed the application in accordance with Article 22 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:

   - to agree to changes to the paediatric investigation plan in the scope set out in the Annex I of this opinion.

   The Norwegian Paediatric Committee member agrees with the above-mentioned recommendation of the Paediatric Committee.

2. The measures and timelines of the paediatric investigation plan and the subset(s) of the paediatric population and condition(s) covered by the waiver are set out in the Annex I.

This opinion is forwarded to the applicant and the Executive Director of the European Medicines Agency, together with its annex and appendix.

Annex I

The subset(s) of the paediatric population and condition(s) covered by the waiver and the measures and timelines of the agreed paediatric investigation plan (PIP)

1. Waiver

1.1. Condition:

Treatment of systemic lupus erythematosus

The waiver applies to:

- the paediatric population from birth to less than 5 years;
- solution for injection, intravenous use, subcutaneous use;
- on the grounds that the disease or condition for which the specific medicinal product is intended does not occur in the specified paediatric subset(s).

2. Paediatric investigation plan

2.1. Condition:

Treatment of systemic lupus erythematosus

2.1.1. Indication(s) targeted by the PIP

- Treatment of active, autoantibody-positive patients with systemic lupus erythematosus (SLE) despite receiving standard of care
- Treatment of active, autoantibody-positive patients with lupus nephritis (LN) despite receiving standard of care

2.1.2. Subset(s) of the paediatric population concerned by the paediatric development

From 5 to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Solution for injection

2.1.4. Measures

Area	Number of measures	Description
Quality-related studies	0	Not applicable
Non-clinical studies	0	Not applicable
Clinical studies	4	**Study 1 (OBS study #1)** Observational study to evaluate the magnitude and distribution of the type I IFN gene signature and additional measures of type I IFN activity in children and adolescents from 5 to less than 18 years of age with pSLE or pLN

		Study 2 (pSLE IV study #1) Placebo controlled, randomised withdrawal study to evaluate pharmacokinetics, efficacy and safety of intravenous anifrolumab in children and adolescents from 5 to less than 18 years of age with pSLE **Study 3 (pSLE + LN IV study #2)** Open-label, non-comparative, randomised withdrawal study to evaluate pharmacokinetics, pharmacodynamics, efficacy, safety and tolerability of intravenous anifrolumab in children and adolescents from 5 to less than 18 years of age pSLE and moderate to severe LN based on biopsy-proven proliferative nephritis and UPCR ≥1 **Study 4 (pSLE SC study #3)** Open-label, single-arm trial to evaluate pharmacokinetics, pharmacodynamics and safety of subcutaneous anifrolumab in children and adolescents from 5 to less than 18 years of age with moderate to severely active pSLE
Extrapolation, modelling and simulation studies	4	**Study 5 (pSLE IV MS Study #1, pSLE)** Modelling and simulation study to project concentration-time profiles of intravenous anifrolumab and gene signature profiles in paediatric SLE patients (with at most mild LN) **Study 6 (pSLE SC MS Study #2 pSLE)** Modelling and simulation study to project concentration-time profiles of subcutaneous anifrolumab and gene signature profiles in paediatric SLE patients (with at most mild LN) **Study 7 (pLN IV MS Study #3 pLN)** Modelling and simulation study to project concentration-time profiles of intravenous anifrolumab and gene signature profiles in paediatric SLE patients with moderate to severe LN **Study 8 (Anifrolumab EXP-1 pSLE - SC route of administration)** Extrapolation study to evaluate the use of subcutaneous anifrolumab in children from 5 to less than 18 years of age with pSLE
Other studies	0	Not applicable
Other measures	0	Not applicable

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety/efficacy issues in relation to paediatric use:	No
Date of completion of the paediatric investigation plan:	By December 2025
Deferral for one or more measures contained in the paediatric investigation plan:	Yes