EMA/2923/2017

European Medicines Agency decision

P/0022/2017

of 30 January 2017

on the acceptance of a modification of an agreed paediatric investigation plan for nanobody directed towards the fusion protein of human respiratory syncytial virus (ALX-0171) (EMEA-001553-PIP01-13-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 decision P/0246/2014 issued on 29 September 2014,

Having regard to the application submitted by Ablynx NV on 26 September 2016 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a deferral,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 16 December 2016, 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 and to the deferral.

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

[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 nanobody directed towards the fusion protein of human respiratory syncytial virus (ALX-0171), nebuliser solution, inhalation use, including changes to the deferral, 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 Ablynx NV, Technologiepark 21, 9052 – Zwijnaarde, Belgium.

EMA/PDCO/647528/2016
London, 16 December 2016

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

EMEA-001553-PIP01-13-M01

Scope of the application

Active substance(s):

Nanobody directed towards the fusion protein of human respiratory syncytial virus (ALX-0171)

Condition(s):

Treatment of lower respiratory tract disease caused by human respiratory syncytial virus (RSV)

Pharmaceutical form(s):

Nebuliser solution

Route(s) of administration:

Inhalation use

Name/corporate name of the PIP applicant:

Ablynx NV

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Ablynx NV submitted to the European Medicines Agency on 26 September 2016 an application for modification of the agreed paediatric investigation plan with a deferral as set out in the European Medicines Agency's decision P/0246/2014 issued on 29 September 2014.

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

The procedure started on 18 October 2016.

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 and to the deferral 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 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

Not applicable.

2. Paediatric investigation plan

2.1. Condition:

Treatment of lower respiratory tract disease caused by human respiratory syncytial virus (RSV)

2.1.1. Indication(s) targeted by the PIP

Treatment of lower respiratory tract disease caused by human respiratory syncytial virus (RSV)

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

From birth to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Nebuliser solution

2.1.4. Measures

Area	Number of measures	Description
Quality-related studies	1	**Study 1** Development of product- and age-specific nebuliser devices which take into consideration paediatric populations requiring or not (non)-invasive ventilation as well as immunocompromised subjects.
Non-clinical studies	2	**Study 2** PK study in juvenile animals. **Study 3** In vivo efficacy testing in a neonatal lamb model.
Clinical studies	6	**Study 4** Randomised, double-blind, placebo-controlled safety, tolerability and PK study in infants and toddlers hospitalised for RSV lower respiratory tract infection, aged 28 days to less than 24 months. **Study 5** deleted in EMEA-001553-PIP01-M01 **Study 6** Randomised, double-blind, placebo-controlled efficacy, safety and PK study in infants and children hospitalised for RSV lower respiratory tract

		infection, including high-risk subjects, aged 28 days to less than 3 years. **Study 7** Randomised, double-blind, placebo-controlled efficacy, safety and PK study in infants and children hospitalised for RSV lower respiratory tract infection and requiring non-invasive and invasive mechanical ventilation, including high-risk subjects, aged 28 days to less than 3 years. **Study 8** deleted in EMEA-001553-PIP01-M01 **Study 9** Randomised, double-blind, placebo-controlled efficacy and safety study in infants and children hospitalised for RSV lower respiratory tract infection, including high-risk subjects, aged 28 days to less than 3 years. **Study 10** Randomised, double-blind, placebo-controlled efficacy and safety study in infants and children at risk of hospitalisation for RSV lower respiratory tract infection, including high-risk subjects, aged 28 days to less than 3 years. **Study 11** Randomised, double-blind, placebo-controlled efficacy and safety study in preterm and term newborn infants aged less than 28days and infants with a history of prematurity, but currently aged 28 days to less than 3 months. **Study 12** deleted in EMEA-001553-PIP01-M01
Extrapolation, modelling and simulation studies	2	**Study 13** Modelling and simulation physiologically-based pharmacokinetic study for dose determination in all planned clinical studies. **Study 14** Extrapolation study to provide guidance on appropriate dosing regimens for immunocompromised subjects aged 0 to less than 18 years.
Other studies		Not applicable.
Other measures		Not applicable.

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety/efficacy issues in relation to paediatric use:	Yes
Date of completion of the paediatric investigation plan:	By September 2022
Deferral for one or more measures contained in the paediatric investigation plan:	Yes