EMA/70884/2022

European Medicines Agency decision

P/0070/2022

of 11 March 2022

on the agreement of a paediatric investigation plan and on the granting of a deferral for CpG 1018/Alum-adjuvanted recombinant SARS-CoV-2 Trimeric Spike (S) protein subunit vaccine (SCB-2019) (EMEA-002987-PIP01-21) 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 Union procedures for the authorisation and supervision of medicinal products for human use and establishing a European Medicines Agency[2],

Having regard to the application submitted by Clover Biopharmaceuticals AUS Pty Ltd on 31 March 2021 under Article 16(1) of Regulation (EC) No 1901/2006 also requesting a deferral under Article 20 of said Regulation,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 21 January 2022, in accordance with Article 17 of Regulation (EC) No 1901/2006 and Article 21 of said Regulation,

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 agreement of a paediatric investigation plan and on the granting of a deferral.

(2) It is therefore appropriate to adopt a decision agreeing a paediatric investigation plan.

(3) It is therefore appropriate to adopt a decision granting a deferral.

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

Has adopted this decision:

Article 1

A paediatric investigation plan for CpG 1018/Alum-adjuvanted recombinant SARS-CoV-2 Trimeric Spike (S) protein subunit vaccine (SCB- 2019), solution for injection, intramuscular use, the details of which are set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices, is hereby agreed.

Article 2

A deferral for CpG 1018/Alum-adjuvanted recombinant SARS-CoV-2 Trimeric Spike (S) protein subunit vaccine (SCB- 2019), solution for injection, intramuscular use, the details of which are set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices, is hereby granted.

Article 3

This decision is addressed to Clover Biopharmaceuticals Ireland Limited, 6th Floor, South Bank House, Barrow Street, DUB LIN4 – Dublin, Ireland.

EMA/PDCO/577358/2021
Amsterdam, 21 January 2022

Opinion of the Paediatric Committee on the agreement of a Paediatric Investigation Plan and a deferral

EMEA-002987-PIP01-21

Scope of the application

Active substance(s):

CpG 1018/Alum-adjuvanted recombinant SARS-CoV-2 Trimeric Spike (S) protein subunit vaccine (SCB-2019)

Condition(s):

Prevention of coronavirus disease 2019 (COVID-19)

Pharmaceutical form(s):

Solution for injection

Route(s) of administration:

Intramuscular use

Name/corporate name of the PIP applicant:

Clover Biopharmaceuticals Ireland Limited

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Clover Biopharmaceuticals AUS Pty Ltd submitted for agreement to the European Medicines Agency on 31 March 2021 an application for a paediatric investigation plan for the above mentioned medicinal product and a deferral under Article 20 of said Regulation.

The procedure started on 25 May 2021.

Supplementary information was provided by the applicant on 7 October 2021.

On 7 October 2021 Clover Biopharmaceuticals AUS Pty Ltd requested to transfer the paediatric investigation plan to Clover Biopharmaceuticals Ireland Limited.

Opinion

1. The Paediatric Committee, having assessed the proposed paediatric investigation plan in accordance with Article 17 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:

   - to agree the paediatric investigation plan in accordance with Article 17(1) of said Regulation;
   - to grant a deferral in accordance with Article 21 of said Regulation.

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

2. The measures and timelines of the agreed 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:

Prevention of coronavirus disease 2019 (COVID-19)

2.1.1. Indication(s) targeted by the PIP

Prevention of coronavirus disease 2019 (COVID-19)

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)

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	3	***Study 1 (CLO-SCB-2019-003)*** Double-blind, randomised, controlled efficacy, safety and immunogenicity study of CpG 1018/Alum-adjuvanted recombinant SARS-CoV-2 Trimeric Spike (S) protein subunit vaccine (SCB-2019) in adolescents from 12 years to less than 18 years of age (and adults) for the prevention of COVID-19 ***Study 2 (CLO-SCB-2019-007)*** Observer-blind, randomised, safety, reactogenicity and immunogenicity study of CpG 1018/Alum-adjuvanted recombinant SARS-CoV-2 Trimeric Spike (S) protein subunit vaccine (SCB-2019) in children from birth to less than 18 years of age for the prevention of COVID-19

		Study 3 (CLO-SCB-2019-012) Open-label, uncontrolled study to evaluate the safety and immunogenicity of CpG 1018/Alum-adjuvanted recombinant SARS-CoV-2 Trimeric Spike (S) protein subunit vaccine (SCB-2019) in immunocompromised children and adolescents from birth to less than 18 years of age for the prevention of COVID-19.
Extrapolation, modelling and simulation studies	0	Not applicable
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 2026
Deferral for one or more measures contained in the paediatric investigation plan:	Yes