EMA/640530/2020

European Medicines Agency decision

P/0480/2020

of 27 November 2020

on the agreement of a paediatric investigation plan and on the granting of a deferral for highly purified single-stranded, 5'-capped mRNA encoding full-length SARS-CoV-2 spike protein (BNT162b2), (EMEA-002861-PIP02-20) 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 application submitted by BioNTech Europe GmbH on 21 September 2020 under Article 16(1) of Regulation (EC) No 1901/2006 also requesting a deferral under Article 20 of said regulation and a waiver under Article 13 of said Regulation,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 25 November 2020, 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.
[2] OJ L 136, 30.4.2004, p. 1.

Has adopted this decision:

Article 1

A paediatric investigation plan for highly purified single-stranded, 5'-capped mRNA encoding full-length SARS-CoV-2 spike protein (BNT162b2) , concentrate for 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 highly purified single-stranded, 5'-capped mRNA encoding full-length SARS-CoV-2 spike protein (BNT162b2) , concentrate for 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 BioNTech Manufacturing GmbH, An der Goldgrube 12, 55131 – Mainz, Germany.

EMA/PDCO/585708/2020
Amsterdam, 25 November 2020

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

EMEA-002861-PIP02-20

Scope of the application

Active substance(s):

Highly purified single-stranded, 5'-capped mRNA encoding full-length SARS-CoV-2 spike protein (BNT162b2)

Condition(s):

Prevention of Coronavirus disease 2019 (COVID-19)

Pharmaceutical form(s):

Concentrate for solution for injection

Route(s) of administration:

Intramuscular use

Name/corporate name of the PIP applicant:

BioNTech Manufacturing GmbH

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, BioNTech Europe GmbH submitted for agreement to the European Medicines Agency on 21 September 2020 an application for a paediatric investigation plan for the above mentioned medicinal product and a deferral under Article 20 of said Regulation and a waiver under Article 13 of said Regulation.

The procedure started on 13 October 2020.

Supplementary information was provided by the applicant on 6 November 2020. The applicant proposed modifications to the paediatric investigation plan and withdrew its request for a waiver.

On 6 November 2020 BioNTech Europe GmbH requested to transfer the paediatric investigation plan to BioNTech Manufacturing GmbH.

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)

Concentrate for 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 (C4591001)** Double blind dose-finding study of safety, tolerability, and immunogenicity of 2 different SARS-CoV-2 vaccine candidates (adults only) (part 1) and placebo-controlled efficacy, safety and immunogenicity study of highly purified single-stranded, 5'-capped mRNA encoding full-length SARS-CoV-2 spike protein (BNT162b2) in adolescents from 12 years to less than 18 years of age (and adults) (part 2) for prevention of COVID-19 **Study 2 (C4591007)** Double blind, controlled, dose-finding safety and immunogenicity study of BNT162b2 in children and adolescents from 5 years to less than 18 years of age for prevention of COVID-19 **Study 3**

		Double blind, controlled, dose-finding, safety and immunogenicity study of BNT162b2 in children from birth to less than 5 years of age for prevention of COVID-19 **Study 4** Open label, uncontrolled, safety and immunogenicity study of BNT162b2 in immunocompromised children from birth to less than 18 years of age for 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 July 2024
Deferral for one or more measures contained in the paediatric investigation plan:	Yes