MHRA
10 South Colonnade
Canary Wharf
London
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United Kingdom

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Decision Cover Letter

Decision of the licensing authority to:

accept change(s) to the agreed paediatric investigation plan (MHRA-100392-PIP01-21-M02) and to the deferral

MHRA-100392-PIP01-21-M03

Scope of the Application

Active Substance(s)

TOZINAMERAN; TOZINAMERAN/ FAMTOZINAMERAN

Condition(s)

Prevention of Coronavirus disease 2019 (COVID-19)

Pharmaceutical Form(s)

Concentrate for solution for injection, Dispersion for injection

Route(s) of Administration

INTRAMUSCULAR USE

Name / Corporate name of the PIP applicant

BioNTech Manufacturing GmbH

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, BioNTech Manufacturing GmbH submitted to the licensing authority on 08/12/2022 17:10 GMT an application for a Modification

The procedure started on 22/12/2022 09:22 GMT

1. The licensing authority, having assessed the application in accordance with the Human Medicines Regulations 2012, decides, as set out in the appended summary report:

to accept change(s) to the agreed paediatric investigation plan and to the deferral

2. The measures and timelines of the paediatric investigation plan are set out in the Annex I.

This decision is forwarded to the applicant, together with its annex and appendix.

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Final Decision Letter

MHRA-100392-PIP01-21-M03

Of 19/01/2023 08:44 GMT

On the adopted decision for TOZINAMERAN; TOZINAMERAN/ FAMTOZINAMERAN (MHRA-100392-PIP01-21-M03) in accordance with the Human Medicines Regulations 2012.

The licensing authority, in accordance with the Human Medicines Regulations 2012, has adopted this decision:

Agreement on modification of a paediatric investigation plan (including modification of a waiver or deferral included in that paediatric investigation plan)

This decision applies to a Modification for TOZINAMERAN; TOZINAMERAN/ FAMTOZINAMERAN, Concentrate for solution for injection, Dispersion for injection , INTRAMUSCULAR USE .

This decision is addressed to BioNTech Manufacturing GmbH, An der Goldgrube 12, Mainz, GERMANY, 55131

ANNEX I

1. Waiver

1.1 Condition:

Not applicable

2. Paediatric Investigation Plan:

2.1 Condition(s):

Prevention of Coronavirus disease 2019 (COVID-19)

2.2 Indication(s) targeted by the PIP:

Prevention of Coronavirus disease 2019 (COVID-19)

2.3 Subset(s) of the paediatric population concerned by the paediatric development:

The paediatric population from birth to less than 18 years of age

2.4 Pharmaceutical Form(s):

Concentrate for solution for injection Dispersion for injection

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	0	Not applicable
Non-Clinical Studies	0	Not applicable
Clinical Studies	6	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, tolerability and immunogenicity study of tozinameran in paediatric subjects from 6 months to less than 18 years of age (and young adults to 30 years of age) for prevention of COVID-19. Study 3 Open label, controlled, dose-finding, safety and immunogenicity study of tozinameran in children from birth to less than 6 months of age for prevention of COVID-19. Study 4 (C4591024) Open label, uncontrolled, safety and immunogenicity study of tozinameran in immunocompromised children from birth to less than 18 years of age for prevention of

		COVID-19. Study 5 (C4591044) Added during procedure MHRA-100392-PIP01-21-M03. Open label, safety, tolerability and immunogenicity study of a booster dose of tozinameran/ famtozinameran in adolescents from 12 years to less than 18 years of age (and adults) for the prevention of COVID-19. Study 6 (C4591048) Added during procedure MHRA-100392-PIP01-21-M03. Observer-blind, randomised, controlled, safety, tolerability and immunogenicity study of a primary series of tozinameran/ famtozinameran in children from 6 months to less than 4 years and 3 months of age (sub study A: SSA), and open label, safety, tolerability and immunogenicity study of a booster dose of tozinameran/ famtozinameran in children from 6 months to less than 12 years age for the prevention of COVID-19 (Sub studies B, C, and D).
Extrapolation, Modeling & Simulation Studies	0	Not applicable
Other Studies	0	Not applicable
Other Measures	0	Not applicable

3. Follow-up, completion and deferral of a PIP:

Concerns on potential long term safety and efficacy issues in relation to paediatric use:	No
Date of completion of the paediatric investigation plan:	31/03/2025
Deferral of one or more studies contained in the paediatric investigation plan:	Yes