MHRA
10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

gov.uk/mhra

Decision Cover Letter

Decision of the licensing authority to:

agree a paediatric investigation plan and grant a deferral and grant a waiver

MHRA-100487-PIP01-22

Scope of the Application

Active Substance(s)

exebacase

Condition(s)

Treatment of Staphylococcus aureus bacteraemia

Pharmaceutical Form(s)

Solution for infusion

Route(s) of Administration

Intravenous use

Name / Corporate name of the PIP applicant

ContraFect Corporation

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, ContraFect Corporation submitted to the licensing authority on 18/03/2022 08:17 GMT an application for a Paediatric Investigation Plan

The procedure started on 20/06/2022 10:59 BST

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 agree a paediatric investigation plan and grant a deferral and grant a waiver

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-100487-PIP01-22

Of 01/07/2022 11:28 BST

On the adopted decision for exebacase (MHRA-100487-PIP01-22) 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 a paediatric investigation plan

This decision applies to a Paediatric Investigation Plan for exebacase, Solution for infusion , Intravenous use .

This decision is addressed to ContraFect Corporation, 28 Wells Avenue, 3rd Floor, Yonkers, New York, UNITED STATES OF AMERICA, NY10701

ANNEX I

1. Waiver

1.1 Condition:

Not applicable

2. Paediatric Investigation Plan:

2.1 Condition(s):

Treatment of Staphylococcus aureus bacteraemia

2.2 Indication(s) targeted by the PIP:

The treatment of Staphylococcus aureus bacteraemia in the setting of right-sided endocarditis, skin and soft tissue, intravascular and/or bone and joint infections, when used in addition to standard-of-care anti-staphylococcal antibiotics in all paediatric age ranges (0 -18 years)

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):

Solution for infusion

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	0	Not applicable
Non-Clinical Studies	0	Not applicable
Clinical Studies	2	Study 1 Double-blind, randomised, placebo-controlled trial to evaluate pharmacokinetics, safety and efficacy of single dose of exebacase as add-on to standard of care compared to placebo in children from 12 years to less than 18 years of age (and adults) with Staphylococcus aureus blood stream infections. Study 2 Investigator-blind, randomised, placebo-controlled trial to evaluate pharmacokinetics, safety and efficacy of single dose of exebacase as add-on to standard of care compared to placebo in children from birth to less than 18 years of age with Staphylococcus aureus blood stream infections, including an open-label safety and pharmacokinetics lead-in study.
Extrapolation, Modeling & Simulation Studies	2	Study 3 Modelling and simulations study to evaluate the use of exebacase in the treatment of Staphylococcus aureus bacteraemia in children from birth to less than 18 years of age with Staphylococcus aureus blood stream infections. Study 4 Extrapolation study to evaluate the use of exebacase in the treatment of Staphylococcus aureus bacteraemia in children from birth to less than 18 years of age with Staphylococcus aureus blood stream infections.
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:	30/06/2028
Deferral of one or more studies contained in the paediatric investigation plan:	Yes