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

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Decision Cover Letter

Decision of the licensing authority to:

agree a paediatric investigation plan and grant a deferral

MHRA-101103-PIP01-23

Scope of the Application

Active Substance(s)

FINERENONE

Condition(s)

Treatment of heart failure

Pharmaceutical Form(s)

Film-coated tablet; Age-appropriate formulation

Route(s) of Administration

ORAL USE

Name / Corporate name of the PIP applicant

Bayer plc

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Bayer plc submitted to the licensing authority on 13/09/2023 16:53 BST an application for a

The procedure started on 11/01/2024 09:05 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 agree a paediatric investigation plan and grant a 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-101103-PIP01-23

Of 13/03/2024 07:20 GMT

On the adopted decision for FINERENONE (MHRA-101103-PIP01-23) 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 for FINERENONE, Film-coated tablet; Age-appropriate formulation , ORAL USE .

This decision is addressed to Bayer plc, 400 South Oak Way, Reading, UNITED KINGDOM, RG2 6AD

ANNEX I

1. Waiver

1.1 Condition:

Not applicable

2. Paediatric Investigation Plan:

2.1 Condition(s):

Treatment of heart failure

2.2 Indication(s) targeted by the PIP:

Treatment of paediatric patients with heart failure and reduced ejection fraction

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):

Film-coated tablet Age-appropriate formulation

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	1	Study 1 Development of an age-appropriate formulation (liquid or solid) for oral and enteral use of finerenone in newborns and infants.
Non-Clinical Studies	1	Study 2 Juvenile toxicity study of finerenone in rats.
Clinical Studies	2	Study 3 Randomised, double-blind, placebo-controlled study to evaluate the safety, tolerability, pharmacokinetics and pharmacodynamics of finerenone as add-on to standard-of-care (SOC) treatment in paediatric patients from 6 months to less than 18 years of age with heart failure (HF) due to dilated cardiomyopathy. Study 4 Open-label extension study to evaluate the safety of finerenone as add-on to standard-of-care (SOC) treatment in paediatric patients from birth to less than 18 years of age with HF due to dilated cardiomyopathy or congenital heart disease.
Extrapolation, Modeling & Simulation Studies	2	Study 5 Physiologically based pharmacokinetic (PBPK) analysis to determine paediatric dosing for finerenone in paediatric patients with HF. Study 6 Population pharmacokinetic/ pharmacodynamic (PopPKPD) analysis to support extrapolation of efficacy of finerenone in paediatric patients with HF.
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:	Yes
Date of completion of the paediatric investigation plan:	31/07/2031
Deferral of one or more studies contained in the paediatric investigation plan:	Yes