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 and grant a waiver

MHRA-100208-PIP01-21

Scope of the Application

Active Substance(s)

Peptide derivative of glucagon-like-peptide 1 and glucagon with fatty acid side chain

Condition(s)

Treatment of non-alcoholic steatohepatitis

Pharmaceutical Form(s)

Solution for injection

Route(s) of Administration

Subcutaneous use

Name / Corporate name of the PIP applicant

Boehringer Ingelheim International GmbH

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Boehringer Ingelheim International GmbH submitted to the licensing authority on 10/11/2021 12:17 GMT an application for a Paediatric Investigation Plan

The procedure started on 18/02/2022 10:00 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 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-100208-PIP01-21

Of 03/03/2022 08:52 GMT

On the adopted decision for Peptide derivative of glucagon-like-peptide 1 and glucagon with fatty acid side chain (MHRA-100208-PIP01-21) 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 Peptide derivative of glucagon-like-peptide 1 and glucagon with fatty acid side chain, Solution for injection , Subcutaneous use .

This decision is addressed to Boehringer Ingelheim International GmbH, Binger Strasse 173, Ingelheim am Rhein, Germany, 55216

ANNEX I

1. Waiver

1.1 Condition:

Treatment of non-alcoholic steatohepatitis The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 8 years of age Pharmaceutical form(s): Solution for injection Route(s) of administration: Subcutaneous use Reason for granting waiver: on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments

2. Paediatric Investigation Plan:

2.1 Condition(s):

Treatment of non-alcoholic steatohepatitis

2.2 Indication(s) targeted by the PIP:

First line treatment of paediatric patients from 8 years to less than 18 years of age with non-alcoholic steatohepatitis (NASH) and liver fibrosis (stages F2-F3)

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

The paediatric population from 8 years to less than 18 years of age

2.4 Pharmaceutical Form(s):

Solution 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	1	Study 1 (1404.0054) Randomised, double blind, parallel group, placebo-controlled study in paediatric subjects (aged from 8 years to less than 18 years) with non-alcoholic steatohepatitis (NASH) and liver fibrosis (stages F2-F3) to establish safety, efficacy, and pharmacokinetics of BI 456906.
Extrapolation, Modeling & Simulation Studies	2	Study 2 Population pharmacokinetic (PK) model to select an appropriate dosing recommendation for the paediatric population Study 3 Population pharmacokinetic (PK) and pharmacokinetic/ pharmacodynamic (PK/PD) models to characterise exposure response relationships.
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:	31/12/2034
Deferral of one or more studies contained in the paediatric investigation plan:	Yes