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 waiver

MHRA-100679-PIP01-22

Scope of the Application

Active Substance(s)

Talazoparib

Condition(s)

Treatment of Ewing Sarcoma

Pharmaceutical Form(s)

Capsule, hard

Route(s) of Administration

ORAL USE

Name / Corporate name of the PIP applicant

Pfizer Limited

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Pfizer Limited submitted to the licensing authority on 05/09/2022 06:16 BST an application for a Paediatric Investigation Plan

The procedure started on 14/02/2023 15:34 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 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-100679-PIP01-22

Of 17/03/2023 07:27 GMT

On the adopted decision for Talazoparib (MHRA-100679-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 Talazoparib, Capsule, hard , ORAL USE .

This decision is addressed to Pfizer Limited, Ramsgate Road, Kent, Sandwich, UNITED KINGDOM, CT13 9NJ

ANNEX I

1. Waiver

1.1 Condition:

Treatment of Ewing Sarcoma The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 12 months of age Pharmaceutical form(s): Capsule, hard Route(s) of administration: ORAL USE Reason for granting waiver: on the grounds that the disease or condition for which the specific medicinal product is intended does not occur in the specified paediatric subset(s).

2. Paediatric Investigation Plan:

2.1 Condition(s):

Treatment of Ewing Sarcoma

2.2 Indication(s) targeted by the PIP:

Talazoparib in combination with liposomal irinotecan (l-IRN) for the treatment of paediatric patients with refractory or recurrent Ewing sarcoma (EWS)

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

The paediatric population from 1 year to less than 18 years of age

2.4 Pharmaceutical Form(s):

Capsule, hard

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	1	Study 1 Development of an instruction manual on preparation and administration of the liquid suspension from the existing pharmaceutical form, capsule, hard.
Non-Clinical Studies	0	Not applicable.
Clinical Studies	1	Study 2 An active controlled, two part trial to evaluate the recommended Phase 2 dose, pharmacokinetics and safety of talazoparib in combination with liposomal irinotecan and temozolomide in combination with liposomal irinotecan in patients from 1 year of age to less than 18 years of age (and adults) with relapsed/ refractory solid malignancies (Part 1), followed by an expansion cohort for patients with homologous recombination repair and double strand breaks signalling defects, and by a randomised controlled Part 2 to evaluate efficacy of talazoparib in combination with liposomal irinotecan compared to temozolomide in combination with liposomal irinotecan in patients from 1 year to less than 18 years of age (and adults) with relapsed/ refractory Ewing sarcoma.
Extrapolation, Modeling & Simulation Studies	1	Study 3 Use of Population Pharmacokinetic analysis for talazoparib to confirm or modify the

		paediatric posology compared to the regimen used in clinical trials.
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:	31/12/2027
Deferral of one or more studies contained in the paediatric investigation plan:	Yes