EMA/328854/2024

European Medicines Agency decision

P/0266/2024

of 17 July 2024

on the acceptance of a modification of an agreed paediatric investigation plan for ribociclib (Kisqali), (EMEA-002765-PIP02-21-M01) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

Disclaimer

This decision does not constitute entitlement to the rewards and incentives referred to in Title V of Regulation (EC) No 1901/2006.

Only the English text is authentic.

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The European Medicines Agency,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use and amending Regulation (EEC) No. 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004[1],

Having regard to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing a European Medicines Agency[2],

Having regard to the European Medicines Agency's decision P/0020/2022 issued on 31 January 2022,

Having regard to the application submitted by Novartis Europharm Limited on 26 February 2024 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a waiver,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 31 May 2024, in accordance with Article 22 of Regulation (EC) No 1901/2006,

Having regard to Article 25 of Regulation (EC) No 1901/2006,

Whereas:

(1) The Paediatric Committee of the European Medicines Agency has given an opinion on the acceptance of changes to the agreed paediatric investigation plan.

(2) It is therefore appropriate to adopt a decision on the acceptance of changes to the agreed paediatric investigation plan.

[1] OJ L 378, 27.12.2006, p.1, as amended.
[2] OJ L 136, 30.4.2004, p. 1, as amended.

Has adopted this decision:

Article 1

Changes to the agreed paediatric investigation plan for ribociclib (Kisqali), film-coated tablet, age-appropriate oral liquid dosage form, oral use, are hereby accepted in the scope set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices.

Article 2

This decision is addressed to Novartis Europharm Limited, Vista Building, Elm Park, Merrion Road, D04A9N6 – Dublin, Ireland.

EMA/PDCO/103150/2024
Amsterdam, 31 May 2024

Opinion of the Paediatric Committee on the acceptance of a modification of an agreed Paediatric Investigation Plan

EMEA-002765-PIP02-21-M01

Scope of the application

Active substance(s):

Ribociclib

Invented name and authorisation status:

See Annex II

Condition(s):

Treatment of neuroblastoma

Pharmaceutical form(s):

Film-coated tablet

Age-appropriate oral liquid dosage form

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

Novartis Europharm Limited

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Novartis Europharm Limited submitted to the European Medicines Agency on 26 February 2024 an application for modification of the agreed paediatric investigation plan with a waiver as set out in the European Medicines Agency's decision P/0020/2022 issued on 31 January 2022

The application for modification proposed changes to the agreed paediatric investigation plan.

The procedure started on 2 April 2024.

Scope of the modification

Some measures and timelines of the Paediatric Investigation Plan have been modified.

Opinion

1. The Paediatric Committee, having assessed the application in accordance with Article 22 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:
    - to agree to changes to the paediatric investigation plan in the scope set out in the Annex I of this opinion.
2. The measures and timelines of the paediatric investigation plan and the subset(s) of the paediatric population and condition(s) covered by the waiver are set out in the Annex I.

This opinion is forwarded to the applicant and the Executive Director of the European Medicines Agency, together with its annexes and appendix.

Annex I

The subset(s) of the paediatric population and condition(s) covered by the waiver and the measures and timelines of the agreed paediatric investigation plan (PIP)

1. Waiver

1.1. Condition:

Treatment of neuroblastoma

The waiver applies to:

- the paediatric population from birth to less than 1 year of age;
- film-coated tablet, age-appropriate oral liquid dosage form, oral use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit as the needs are already covered.

2. Paediatric investigation plan

2.1. Condition:

Treatment of neuroblastoma

2.1.1. Indication(s) targeted by the PIP

Treatment of relapsed or refractory neuroblastoma (NB) in patients aged 12 months and above in combination with temozolomide and topotecan (TOTEM).

2.1.2. Subset(s) of the paediatric population concerned by the paediatric development

From 1 year to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Film coated tablet, age-appropriate oral liquid dosage form

2.1.4. Measures

Area	Description
Quality-related studies	**Study 1** Deleted during EMEA-002765-PIP02-21-M01
Non-clinical studies	**Study 2** Definitive juvenile toxicity study
Clinical studies	**Study 3** Open-label, single arm trial (Part A) to determine the recommended Phase 2 dose (RP2D) and evaluate pharmacokinetics, safety and activity of ribociclib as add-on to topotecan and temozolomide (TOTEM) in children from 1 year to less than 18 years of age (and adults) with relapsed or refractory neuroblastoma (and other solid tumours).

	Study 4 Deleted during EMEA-002765-PIP02-21-M01 **Study 5** Deleted during EMEA-002765-PIP02-21-M01
Extrapolation, modelling and simulation studies	**Study 6** Deleted during EMEA-002765-PIP02-21-M01
Other studies	Not applicable
Other measures	Not applicable

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety/efficacy issues in relation to paediatric use:	No
Date of completion of the paediatric investigation plan:	By December 2025
Deferral for one or more measures contained in the paediatric investigation plan:	No

Annex II

Information about the authorised medicinal product

Information provided by the applicant:

Condition(s) and authorised indication(s)

1. Treatment of breast cancer

Authorised indication(s):

- Treatment of women with hormone receptor (HR) positive, human epidermal growth factor receptor 2 (HER2) negative locally advanced or metastatic breast cancer in combination with an aromatase inhibitor or fulvestrant as initial endocrine-based therapy, or in women who have received prior endocrine therapy.

  In pre or perimenopausal women, the endocrine therapy should be combined with a luteinising hormone releasing hormone (LHRH) agonist

  - Invented name(s): Kisqali
  - Authorised pharmaceutical form(s): Film-coated tablet
  - Authorised route(s) of administration: Oral use
  - Authorised via centralised procedure