



Brussels, 9.2.2024
C(2024) 975 final

COMMISSION IMPLEMENTING DECISION

of 9.2.2024

granting marketing authorisation under Regulation (EC) No 726/2004 of the European Parliament and of the Council for "Skyclarys - omaveloxolone", an orphan medicinal product for human use

(Text with EEA relevance)

(ONLY THE ENGLISH TEXT IS AUTHENTIC)

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THE EUROPEAN COMMISSION,

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

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 Agency¹, and in particular Article 10(2) thereof,

Having regard to Regulation (EC) No 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products², and in particular Article 5(12) thereof,

Having regard to the application submitted by Reata Ireland Limited, on 28 December 2022, under Article 4(1) of Regulation (EC) No 726/2004,

Having regard to the opinions of the European Medicines Agency, formulated on 14 December 2023 by the Committee for Medicinal Products for Human Use and on 15 December 2023 by the Committee for Orphan Medicinal Products,

Whereas:

- (1) Commission Decision C(2018)4182(final), adopted in accordance with Regulation (EC) No 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products designated "Omaveloxolone" as an orphan medicinal product.
- (2) The orphan medicinal product "Skyclarys - omaveloxolone" complies with the requirements set out in Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use³.
- (3) It is therefore appropriate to authorise its placing on the market.
- (4) The Committee for Medicinal Products for Human Use considered that "omaveloxolone" is a new active substance.

¹ OJ L 136, 30.4.2004, p. 1.

² OJ L 18, 22.1.2000, p. 1.

³ OJ L 311, 28.11.2001, p. 67.

- (5) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Medicinal Products for Human Use,

HAS ADOPTED THIS DECISION:

Article 1

The marketing authorisation provided for in Article 3 of Regulation (EC) No 726/2004 is granted for the orphan medicinal product "Skyclarys - omaveloxolone", the characteristics of which are summarised in Annex I to this Decision. "Skyclarys - omaveloxolone" shall be registered in the Union Register of Medicinal Products under number EU/1/23/1786.

Article 2

The marketing authorisation concerning the medicinal product referred to in Article 1 shall be subject to compliance with the conditions set out in Annex II and, in particular, with those relating to manufacture and importation, control and issue.

Article 3

The labelling and package leaflet concerning the orphan medicinal product referred to in Article 1 shall conform to Annex III.

Article 4

The period of validity of the marketing authorisation shall be five years from the date of notification of this Decision.

Article 5

This Decision is addressed to Reata Ireland Limited, Block A, George's Quay Plaza, George's Quay, Dublin 2, D02 E440, Ireland.

Done at Brussels, 9.2.2024

For the Commission

Sandra GALLINA

Director-General

