EUROPEAN
COMMISSION

Brussels, 17.7.2023
C(2023)4949 (final)

COMMISSION IMPLEMENTING DECISION

of 17.7.2023

transferring and amending the marketing authorisation granted by Decision C(2016)3278(final) for "Strimvelis - autologous CD34+ enriched cell fraction that contains CD34+ cells transduced with retroviral vector that encodes for the human ADA cDNA sequence", an orphan medicinal product for human use

(Text with EEA relevance)

(ONLY THE ITALIAN AND DUTCH TEXTS ARE 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 Agency[1],

Having regard to Commission Regulation (EC) No 2141/96 of 7 November 1996 concerning the examination of an application for the transfer of a marketing authorisation for a medicinal product falling within the scope of Council Regulation (EEC) No 2309/93[2], and in particular Article 6 thereof,

Having regard to the application submitted by Orchard Therapeutics (Netherlands) B.V. on 16 May 2023 under Article 3 of Regulation (EC) No 2141/96,

Having regard to Commission Regulation (EC) No 1234/2008 of 24 November 2008 concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products[3],

Having regard to the changes to the terms of the decision granting the marketing authorisation requested by Orchard Therapeutics (Netherlands) B.V. in accordance with Regulation (EC) No 1234/2008,

Having regard to the opinion of the European Medicines Agency, formulated on 2 June 2023 on the transfer of a marketing authorisation,

Whereas:

(1) The medicinal product "Strimvelis - autologous CD34+ enriched cell fraction that contains CD34+ cells transduced with retroviral vector that encodes for the human ADA cDNA sequence", entered in the Union Register of Medicinal Products under the number EU/1/16/1097 and authorised by Commission Decision C(2016)3278(final) of 26 May 2016, remains in compliance with the requirements set

[1] OJ L 136, 30.4.2004, p. 1.
[2] OJ L 286, 8.11.1996, p. 6.
[3] OJ L 334, 12.12.2008, p. 7.

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 use[4] .

(2) A change of holder of the marketing authorisation for which the transfer application is made is a change of an administrative nature, which does not affect the scientific characteristics of the medicinal product already authorised.

(3) It is appropriate to set the date by which all the operations resulting from the transfer of the marketing authorisation must be completed.

(4) The European Medicines Agency's opinion is favourable to the transfer and the variation of the terms of the decision granting the marketing authorisation as submitted by the marketing authorisation holder.

(5) Decision C(2016)3278(final) should therefore be amended accordingly. The Union Register of Medicinal Products should also be updated.

(6) For the sake of clarity and transparency, it is appropriate, following the amendment of part or parts of the Annexes, to provide for a consolidated version thereof. The Annexes to Decision C(2016)3278(final) should therefore be replaced.

HAS ADOPTED THIS DECISION:

Article 1

The marketing authorisation granted by Decision C(2016)3278(final) of 26 May 2016 to Orchard Therapeutics (Netherlands) B.V. for the medicinal product "Strimvelis - autologous CD34+ enriched cell fraction that contains CD34+ cells transduced with retroviral vector that encodes for the human ADA cDNA sequence", entered in the Union Register of Medicinal Products under No EU/1/16/1097, is transferred to Fondazione Telethon ETS.

Article 2

Decision C(2016)3278(final) is amended as follows:

1) Annex I is replaced by the text set out in Annex I to this Decision;

2) Annex II is replaced by the text set out in Annex II to this Decision;

3) Annex III is replaced by the text set out in Annex III to this Decision.

Article 3

1. The transfer referred to in Article 1 shall be authorised from the date of notification of this Decision.

2. All the operations resulting from this transfer must be completed by 1 September 2023 at the latest.

[4] OJ L 311, 28.11.2001, p. 67.

Article 4

This Decision is addressed to:
1. Fondazione Telethon ETS, Via Varese 16/B, 00185 Roma, Italia
and
2. Orchard Therapeutics (Netherlands) B.V., Basisweg 10, 1043 AP Amsterdam, Noord-Holland, Nederland.

Done at Brussels, 17.7.2023

For the Commission

Sandra GALLINA
Director-General