EUROPEAN
COMMISSION

Brussels, 24.3.2022
C(2022) 1974 (final)

COMMISSION IMPLEMENTING DECISION

of 24.3.2022

withdrawing, at the holder's request, the conditional marketing authorisation granted by Decision C(2019) 4181(final) for "Zynteglo - betibeglogene autotemcel", an orphan medicinal product for human use

(Text with EEA relevance)

(ONLY THE DUTCH 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 Agency[1],

Having regard to the application submitted by bluebird bio (Netherlands) B.V. on 10 December 2021 with a view to the withdrawal of the marketing authorisation for the medicinal product "Zynteglo - betibeglogene autotemcel",

Whereas:

(1) The placing on the market of the medicinal product "Zynteglo - betibeglogene autotemcel", which is entered in the Union Register of Medicinal Products under the number EU/1/19/1367 was authorised by Commission Decision C(2019) 4181(final) of 29 May 2019.

(2) Following the holder's request, that authorisation should be withdrawn,

HAS ADOPTED THIS DECISION:

Article 1

At the holder's request, the marketing authorisation granted by Decision C(2019) 4181(final) of 29 May 2019 for the medicinal product "Zynteglo - betibeglogene autotemcel" is withdrawn.

Article 2

The withdrawal referred to in Article 1 shall be applicable with effect from 15 April 2022.

[1] OJ L 136, 30.4.2004, p. 1.

Article 3

This Decision is addressed to bluebird bio (Netherlands) B.V., Stadsplateau 7, WTC Utrecht, 3521 AZ Utrecht, Nederland.

Done at Brussels, 24.3.2022

For the Commission

Sandra GALLINA
Director-General