EUROPEAN
COMMISSION

Brussels, 27.7.2020
C(2020)5231 (final)

COMMISSION IMPLEMENTING DECISION

of 27.7.2020

relating to the designation of "Imetelstat sodium" as an orphan medicinal product under Regulation (EC) No 141/2000 of the European Parliament and of the Council

(Text with EEA relevance)

(ONLY THE GERMAN 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 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products[1], and in particular the first sentence of Article 5(8) thereof,

Having regard to the application submitted by Parexel International GmbH on 20 March 2020 under Article 5(1) of Regulation (EC) No 141/2000,

Having regard to the favourable opinion of the European Medicines Agency, drawn up on 18 June 2020 by the Committee for Orphan Medicinal Products and received by the Commission on 25 June 2020,

Whereas:

(1) The application submitted by Parexel International GmbH concerning the medicinal product “Imetelstat sodium” was validated on 23 April 2020 under Article 5(4) of Regulation (EC) No 141/2000.

(2) "Imetelstat sodium" meets the designation criteria referred to in Article 3(1) of Regulation (EC) No 141/2000.

(3) The application should therefore be accepted,

HAS ADOPTED THIS DECISION:

Article 1

The medicinal product “Imetelstat sodium” is designated as an orphan medicinal product for the indication: Treatment of myelodysplastic syndromes. It shall be entered in the Community Register of Orphan Medicinal Products under number EU/3/20/2305.

Article 2

The European Medicines Agency shall make available to all interested parties the opinion of the Committee on Orphan Medicinal Products referred to in this Decision.

[1] OJ L 18, 22.1.2000, p.1.

Article 3

This Decision is addressed to Parexel International GmbH, Spandauer Damm 130, Charlottenburg, 14050 Berlin, Deutschland.

Done at Brussels, 27.7.2020

For the Commission

Anne BUCHER
Director-General