EUROPEAN
COMMISSION

Bruxelles, 14.10.2016
C(2016)6743 (final)

COMMISSION IMPLEMENTING DECISION

of 14.10.2016

relating to the designation of "Fenretinide" 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 Clinipace GmbH on 21 June 2016 under Article 5(1) of Regulation (EC) No 141/2000,

Having regard to the favourable opinion of the European Medicines Agency, drawn up on 8 September 2016 by the Committee for Orphan Medicinal Products and received by the Commission on 20 September 2016,

Whereas:

(1) The application submitted by Clinipace GmbH concerning the medicinal product “Fenretinide” was validated on 18 July 2016 under Article 5(4) of Regulation (EC) No 141/2000.

(2) "Fenretinide" 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 “Fenretinide” is designated as an orphan medicinal product for the indication: Treatment of peripheral T-cell lymphoma. It shall be entered in the Community Register of Orphan Medicinal Products under number EU/3/16/1751.

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 Clinipace GmbH, Helfmann-Park 10, 65760 Eschborn, Deutschland.

Done at Brussels, 14.10.2016

For the Commission

Xavier PRATS MONNÉ
Director-General