



COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 15-II-2007
C(2007)540

NOT FOR PUBLICATION

COMMISSION DECISION

of 15-II-2007

relating to the designation under Regulation (EC) No 141/2000 of the European Parliament and of the Council of "Autologous dendritic cells pulsed with autologous tumour cell lysate" as an orphan medicinal product

(ONLY THE DUTCH TEXT IS AUTHENTIC)

COMMISSION DECISION

of 15-II-2007

relating to the designation under Regulation (EC) No 141/2000 of the European Parliament and of the Council of "Autologous dendritic cells pulsed with autologous tumour cell lysate" as an orphan medicinal product

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,
Having regard to Regulation (EC) No 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products¹, and in particular the first sentence of Article 5(8) thereof,

Having regard to the application submitted by Dorian Regulatory Affairs BV on 27 September 2006 under Article 5(1) of Regulation (EC) No 141/2000,

Having regard to the favourable opinion of the European Medicines Agency, drawn up on 10 January 2007 by the Committee for Orphan Medicinal Products and received by the Commission on 24 January 2007,

Whereas:

- (1) The application submitted by Dorian Regulatory Affairs BV concerning the medicinal product "Autologous dendritic cells pulsed with autologous tumour cell lysate" was validated on 10 November 2006 under Article 5(4) of Regulation (EC) No 141/2000.
- (2) "Autologous dendritic cells pulsed with autologous tumour cell lysate" 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 "Autologous dendritic cells pulsed with autologous tumour cell lysate" is designated as an orphan medicinal product for the indication: Treatment of glioma. It shall be entered in the Community Register of Orphan Medicinal Products under number EU/3/07/431.

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 Dorian Regulatory Affairs BV, Soestdijkerstraatweg 7, 1213 VP Hilversum, The Netherlands.

Done at Brussels, 15-II-2007

For the Commission
Heinz ZOUREK
Director-General