

## COMMISSION DECISION

of 29.10.2008

**concerning the transfer of the designation of "Tobramycin (liposomal)" as an orphan medicinal product under Regulation (EC) No 141/2000 of the European Parliament and of the Council**

**(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 products<sup>1</sup>, and in particular the first sentence of Article 5(8) thereof,

Having regard to the application submitted on 11 August 2008 by EUCRO GmbH & Co. KG under Article 5(11) of Regulation (EC) No 141/2000,

Having regard to the opinion of the European Medicines Agency,

Whereas:

- (1) By Decision C(2006)1643 of 11 April 2006 the medicinal product "Tobramycin (liposomal)" was designated as an orphan medicinal product and entered in the Community Register of Orphan Medicinal Products pursuant to Article 5(9) of Regulation (EC) No 141/2000.
- (2) A change of designation holder is a change of an administrative nature, which does not affect the scientific characteristics of the medicinal product already designated as an orphan medicinal product.
- (3) The application should therefore be granted,

HAS ADOPTED THIS DECISION:

### *Article 1*

The designation of the medicinal product "Tobramycin (liposomal)" as an orphan medicinal product, entered in the Community Register of Orphan Medicinal Products under number EU/3/06/366 and held by EUCRO GmbH & Co. KG, is transferred to Axentis Pharma Limited.

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<sup>1</sup> OJ L 18, 22.1.2000, p.1.

*Article 2*

This Decision is addressed to:

1. Axentis Pharma Limited, Carpenter Court, 1 Maple Road, Bramhall, Stockport, Cheshire SK7 2DH, United Kingdom

and

2. EUCRO GmbH & Co. KG, Stresemannallee 6, 41460 Neuss, Deutschland.

Done at Brussels, 29.10.2008

*For the Commission*

*Heinz ZOUREK*

*Director-General*

