EUROPEAN
COMMISSION

Brussels, 13.10.2023
C(2023)7041 (final)

**COMMISSION IMPLEMENTING DECISION**

**of 13.10.2023**

**relating to the designation of "Eplontersen" 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 SWEDISH 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 AstraZeneca AB on 19 May 2023 under Article 5(1) of Regulation (EC) No 141/2000,

Having regard to the favourable opinion of the European Medicines Agency, drawn up on 7 September 2023 by the Committee for Orphan Medicinal Products and received by the Commission on 18 September 2023,

Whereas:

(1) The application submitted by AstraZeneca AB concerning the medicinal product “Eplontersen” was validated on 13 June 2023 under Article 5(4) of Regulation (EC) No 141/2000.

(2) "Eplontersen" 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 “Eplontersen” is designated as an orphan medicinal product for the indication: Treatment of transthyretin-mediated amyloidosis. It shall be entered in the Community Register of Orphan Medicinal Products under number EU/3/23/2828.

*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 AstraZeneca AB, 151 85 Södertälje, Sverige.

Done at Brussels, 13.10.2023

*For the Commission*

*Sandra GALLINA*
*Director-General*