EUROPEAN
COMMISSION

Brussels, 12.1.2024
C(2024)317 (final)

COMMISSION IMPLEMENTING DECISION

of 12.1.2024

relating to the designation of "Methyl-(1-{[6-{[(1S)-1-cyclopropylethyl]amino}-2-(pyrazolo[5,1-b][1,3]thiazol-7-yl)-pyrimidin-4-yl]carbonyl}piperidin-4-yl)carbamate mono(4-methylbenzenesulfonate)" 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 DUTCH 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 Syneos Health Netherlands B.V. on 28 August 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 December 2023 by the Committee for Orphan Medicinal Products and received by the Commission on 14 December 2023,

Whereas:

(1) The application submitted by Syneos Health Netherlands B.V. concerning the medicinal product "Methyl-(1-{[6-{[(1S)-1-cyclopropylethyl]amino}-2-(pyrazolo[5,1-b][1,3]thiazol-7-yl)-pyrimidin-4-yl]carbonyl}piperidin-4-yl)carbamate mono(4-methylbenzenesulfonate)" was validated on 14 September 2023 under Article 5(4) of Regulation (EC) No 141/2000.

(2) "Methyl-(1-{[6-{[(1S)-1-cyclopropylethyl]amino}-2-(pyrazolo[5,1-b][1,3]thiazol-7-yl)-pyrimidin-4-yl]carbonyl}piperidin-4-yl)carbamate mono(4-methylbenzenesulfonate)" 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 "Methyl-(1-{[6-{[(1S)-1-cyclopropylethyl]amino}-2-(pyrazolo[5,1-b][1,3]thiazol-7-yl)-pyrimidin-4-yl]carbonyl}piperidin-4-yl)carbamate mono(4-methylbenzenesulfonate)" is designated as an orphan medicinal product for the indication:

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

Treatment of eosinophilic granulomatosis with polyangiitis. It shall be entered in the Community Register of Orphan Medicinal Products under number EU/3/23/2882.

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.

Article 3

This Decision is addressed to Syneos Health Netherlands B.V., De Entree 99-197, 1101 HE Amsterdam, Noord-Holland, Nederland.

Done at Brussels, 12.1.2024

For the Commission

Sandra GALLINA
Director-General