EUROPEAN
COMMISSION

Brussels, 10.4.2019
C(2019) 2938 final

COMMISSION IMPLEMENTING DECISION

of 10.4.2019

concerning the transfer of the designation of "Acetylleucine" 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 ENGLISH 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 on 19 March 2019 by IntraBio Ltd under Article 5(11) of Regulation (EC) No 141/2000,

Having regard to the opinion of the European Medicines Agency, formulated on 19 March 2019 on the transfer of an orphan medicinal product designation,

Whereas:

(1) By Decision C(2018)5731(final) of 24 August 2018 the medicinal product "Acetylleucine" 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 "Acetylleucine" as an orphan medicinal product, entered in the Community Register of Orphan Medicinal Products under number EU/3/18/2059 and held by IntraBio Ltd, is transferred to IntraBio Ireland Ltd.

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

Article 2

This Decision is addressed to:
1. IntraBio Ireland Ltd, 10 Earlsfort Terrace, Dublin 2, Co. Dublin, D02 T380, Ireland
and
2. IntraBio Ltd, University of Oxford Begbroke Science Park, Begbroke Hill, Woodstock Road, Begbroke, Oxfordshire OX5 1PF, United Kingdom.

Done at Brussels, 10.4.2019

For the Commission

Anne BUCHER
Director-General

CERTIFIED COPY
For the Secretary-General,

Jordi AYET PUIGARNAU
Director of the Registry
EUROPEAN COMMISSION