EMA/557965/2016

# European Medicines Agency decision

P/0246/2016

of 12 September 2016

on the granting of a product specific waiver for allogeneic human neural stem cells genetically modified to express c-MycER$^{TAM}$, a c-Myc and modified oestrogen receptor fusion protein (CTX0E03) (EMEA-001969-PIP01-16) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

**Only the English text is authentic.**

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The European Medicines Agency,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use and amending Regulation (EEC) No. 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004[1],

Having regard to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency[2],

Having regard to the application submitted by ReNeuron Ltd on 18 April 2016 under Article 13 of Regulation (EC) No 1901/2006,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 22 July 2016 in accordance with Article 13 of Regulation (EC) No 1901/2006,

Having regard to Article 25 of Regulation (EC) No 1901/2006,

Whereas:

(1) The Paediatric Committee has given an opinion on the granting of a product specific waiver.

(2) It is therefore appropriate to adopt a decision granting a waiver.

[1] OJ L 378, 27.12.2006, p.1.
[2] OJ L 136, 30.4.2004, p. 1.

Has adopted this decision:

***Article 1***

A waiver for allogeneic human neural stem cells genetically modified to express c-MycER$^{TAM}$, a c-Myc and modified oestrogen receptor fusion protein (CTX0E03), suspension for injection, intracerebral use, the details of which are set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices, is hereby granted.

***Article 2***

This decision is addressed to ReNeuron Ltd, Pencoed Business Park, CF35 5HY - Pencoed, United Kingdom.

EMA/PDCO/350673/2016
London, 22 July 2016

# Opinion of the Paediatric Committee on the granting of a product-specific waiver

EMEA-001969-PIP01-16

## Scope of the application

**Active substance(s):**

Allogeneic human neural stem cells genetically modified to express c-MycER$^{TAM}$, a c-Myc and modified oestrogen receptor fusion protein (CTX0E03)

**Condition(s):**

Treatment of cerebral infarction

**Pharmaceutical form(s):**

Suspension for injection

**Route(s) of administration:**

Intracerebral use

**Name/corporate name of the PIP applicant:**

ReNeuron Ltd

## Basis for opinion

Pursuant to Article 13 of Regulation (EC) No 1901/2006 as amended, ReNeuron Ltd submitted to the European Medicines Agency on 18 April 2016 an application for a product-specific waiver on the grounds set out in Article 11 of said Regulation for the above mentioned medicinal product.

The procedure started on 24 May 2016.

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## Opinion

1. The Paediatric Committee, having assessed the waiver application in accordance with Article 13 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:

   - to grant a product-specific waiver for all subsets of the paediatric population and the above mentioned condition(s) in accordance with Article 11(1)(a) of said Regulation, on the grounds that the specific medicinal product is likely to be ineffective or unsafe in part or all of the paediatric population.

   The Norwegian Paediatric Committee member agrees with the above-mentioned recommendation of the Paediatric Committee.

2. The grounds for the granting of the waiver are set out in Annex I.

This opinion is forwarded to the applicant and the Executive Director of the European Medicines Agency, together with its annex and appendix.

# Annex I

# Grounds for the granting of the waiver

# 1. Waiver

## *1.1. Condition:*

Treatment of cerebral infarction

The waiver applies to:

- all subsets of the paediatric population from birth to less than 18 years of age;
- for suspension for injection, intracerebral use;
- on the grounds that the specific medicinal product is likely to be unsafe.