



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

EMA/319282/2024

## European Medicines Agency decision P/0237/2024

of 18 July 2024

on the granting of a product specific waiver for allogeneic skin-derived ABCB5-positive dermal mesenchymal stromal cells (Amesandar), (EMA-002875-PIP02-24) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

**Only the English text is authentic.**



# European Medicines Agency decision

P/0237/2024

of 18 July 2024

on the granting of a product specific waiver for allogeneic skin-derived ABCB5-positive dermal mesenchymal stromal cells (Amesandar), (EMA-002875-PIP02-24) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

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<sup>1</sup>,

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

Having regard to the application submitted by RHEACELL GmbH & Co. KG on 22 February 2024 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 31 May 2024 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.

Has adopted this decision:

## **Article 1**

A waiver for allogeneic skin-derived ABCB5-positive dermal mesenchymal stromal cells (Amesandar), all pharmaceutical forms, all routes of administration, 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 RHEACELL GmbH & Co. KG, Im Neuenheimer Feld 517, 69120 - Heidelberg, Germany.

---

<sup>1</sup> OJ L 378, 27.12.2006, p.1, as amended.

<sup>2</sup> OJ L 136, 30.4.2004, p. 1, as amended.

EMA/PDCO/101815/2024  
Amsterdam, 31 May 2024

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

EMA-002875-PIP02-24

### Scope of the application

**Active substance(s):**

Allogeneic skin-derived ABCB5-positive dermal mesenchymal stromal cells

**Invented name and authorisation status:**

See Annex II

**Condition(s):**

Treatment of venous leg ulcer

**Pharmaceutical form(s):**

All pharmaceutical forms

**Route(s) of administration:**

All routes of administration

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

RHEACELL GmbH & Co. KG

### Basis for opinion

Pursuant to Article 13 of Regulation (EC) No 1901/2006 as amended, RHEACELL GmbH & Co. KG submitted to the European Medicines Agency on 22 February 2024 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 2 April 2024.

## 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)(b) of said Regulation, on the grounds that the disease or condition for which the specific medicinal product is intended does not occur in the specified subset(s) of the paediatric population.
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 annexes and appendix.

## **Annex I**

### **Grounds for the granting of the waiver**

# 1. Waiver

## **1.1. Condition:**

Treatment of venous leg ulcer

The waiver applies to:

- all subsets of the paediatric population from birth to less than 18 years of age;
- all pharmaceutical forms, all routes of administration;
- on the grounds that the disease or condition for which the specific medicinal product is intended does not occur in the specified paediatric subset(s).

## **Annex II**

### **Information about the authorised medicinal product**

***Information provided by the applicant:***

**Condition(s) and authorised indication(s)**

1. Treatment of venous leg ulcers (VLUs)

Authorised indication(s):

- For the local treatment of chronic venous ulcers (CVUs) due to chronic venous insufficiency (CVI) at a dose of  $1 \times 10^6$  cells/cm<sup>2</sup> wound area in patients with CVUs, where no improvement is seen, despite of optimal phlebological therapy (therapy-resistant non-healing CVUs).
  - Invented name(s): Amesanar
  - Authorised pharmaceutical form(s): Cutaneous suspension
  - Authorised route(s) of administration: Cutaneous use
  - Authorised via national procedure in Germany (only), according to §4b of the German Arzneimittelgesetz (AMG) (German Medicines Act); PEI approval number: PEI.A.12060.01.1