



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

17 June 2013  
EMA/370710/2013  
Patient Health Protection

## Scientific recommendation on classification of advanced therapy medicinal products

Article 17 – Regulation (EC) No 1394/2007

**Disclaimer:** This document is a summary for public release of a scientific recommendation on classification of advanced therapy medicinal products. The original text adopted by the Committee for Advanced Therapies (CAT) has been redacted to delete commercially confidential information.

The present scientific recommendation refers exclusively to the case as presented to the European Medicines Agency (EMA) without prejudice to future evaluations by the Agency.

This scientific recommendation is not binding and is without prejudice to any decision taken by Member State competent authorities on matters falling within their own remits.

### Short description of the proposed active substance

Autologous expanded CD34+ stem cells

### Brief description of the proposed finished product

Suspension of expanded CD34+ Stem Cells conditioned in 3 syringes for an autologous endocardiac injection.

### Proposed indication

Injection after angioplasty and stents grafting procedure in patients with an Acute Myocardial Infarction (AMI). Therapeutic use in patients with left Ventricle Ejection Fraction below or equal to 45%.



## **EMA/CAT comment**

### ***Consideration of Article 1(2) of Directive 2001/83/EC***

- The product consists of autologous ex vivo expanded CD34+ cells which can be considered a 'substance' in the meaning of the pharmaceutical legislation (in accordance with article 1(3) of Directive 2001/83/EC), administered to humans with a view to restoring physiological function(s) by exerting a metabolic and/or a pharmacological action.
- The product is presented as having properties for treating disease in human being.
- According to Article 1(2), the restoration, correction or modification of the physiological function is to be mediated by the substances that exert "a pharmacological, immunological or metabolic action". As the product consists of CD34+ cells, it can be agreed that the product acts via metabolic and/or a pharmacological means.

### ***Fulfilment of Article 2(1) of Regulation (EC) No 1394/2007***

- The product consists of manipulated (expanded) autologous peripheral blood CD34+ cells.
- The cells are considered to be 'engineered' as they have been subject to substantial manipulation (ex vivo expansion), so that biological characteristics, physiological functions or structural properties relevant for the intended regeneration, repair or replacement are achieved (i.e. regeneration of damaged tissue).
- The product is administered to human beings with a view to relieve damage induced by Acute Myocardial Infarction (AMI), via differentiation of CD34+ stem cells into cardiomyocytes.

Based on the above considerations, it is considered that the product falls within the definition of an advanced therapy medicinal product (ATMP), and - tissue engineered product (TEP).

## **EMA/CAT conclusion**

On the basis that:

- the product consists of autologous ex vivo expanded CD34+ cells;
- these CD34+ cells are substantially manipulated so that biological characteristics, physiological functions or structural properties relevant for the intended regeneration, repair or replacement are achieved;
- the product is intended for the treatment of Acute Myocardial Infarction (AMI) via regeneration of damaged tissue;

the EMA/CAT considers that the product falls within the definition of a tissue engineered product as provided in Article 2(1)(a) of Regulation (EC) No 1394/2007.