EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

13 November 2017
EMA/751423/2017
Inspections, Human Medicines Pharmacovigilance & Committees Division

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.

It is stressed that the scientific recommendation on advanced therapy classification does not amount to any endorsement of the plausibility of the product, including the mode of action or therapeutic indication(s) claimed by the applicant.

Brief description (or name when available) of the active substance(s)

Allogenic adipose-derived stem cells (ADSC) differentiated *in vitro* towards the cardiovascular lineage.

Brief description of the finished product

Allogenic adipose-derived stem cells (ADSC) differentiated *in vitro* towards the cardiovascular lineage and combined with carrier and implanting device.

Proposed indication

To restore cardiac function post myocardic infarction.

EMA / CAT conclusion

The procedure was finalised on 17 October 2017 for the following recommendation.

On the basis that the product:

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- contains engineered cells, which have been subject to substantial manipulation, so that biological characteristics, physiological functions or structural properties relevant for the intended regeneration, repair or replacement are achieved and is presented as having properties for and is used in human beings to regenerate a human tissue and it incorporates, as an integral part of the product, one medical device (carrier),

the EMA/CAT considers that the product falls within the definition of a tissue engineered product, combined advanced therapy medicinal product as provided in Article 2(1)(d) of Regulation (EC) 1394/2007.