EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

31 January 2018
EMA/65631/2018
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)

Autologous adipose-derived stem cells seeded on a collagen matrix scaffold.

Brief description of the finished product

Autologous adipose-derived stem cells obtained from a stromal vascular fraction seeded on a collagen matrix scaffold.

Proposed indication

Treatment of cancer-related lymphedema in breast cancer patients.

EMA / CAT conclusion

The procedure was finalised on 20 December 2017 for the following recommendation.

On the basis that:

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- the cells applied are used in human beings with a view to regenerating or replacing a human tissue (support lymph-angiogenesis) and are administered in combination with the BioBridge collagen matrix scaffold which is an integral requirement for the action of the cells,

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