EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

23 April 2019
EMA/234927/2019
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)

Cultured autologous adipose-derived stem cells.

Brief description of the finished product

Adipose-derived stem cells seeded into the polypropylene conduit mimicking the extracellular environment of the urinary tract.

Proposed indication

Urinary diversion in patients requiring radical cystectomy for the treatment of bladder cancer.

EMA/CAT conclusion

The procedure was finalised on 6 February 2019 for the following recommendation.

On the basis that:

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

- the product contains viable, undifferentiated adipose-derived stem cells seeded onto a tubular scaffold composed of absorbable and non-absorbable biomaterials;
- the cells have been substantially manipulated (cultured), so that biological characteristics, physiological functions or structural properties relevant for the intended regeneration, repair or replacement are achieved, and is administered to human beings with a view to regenerating, repairing and replacing a human tissue;
- the product incorporates, as an integral part of the product, the non-absorbable polypropylene tubular scaffold, which can be considered a medical device as it is intended to be used in human beings for replacing some of the anatomical structures of the urinary tract

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) of Regulation (EC) 1394/2007.