EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

26 January 2015
EMA/555245/2015
Procedure Management & Business Support Division
Scientific Committee Support Department

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

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

Adipose-derived mesenchymal stem cells

Brief description of the finished product

Ex vivo expanded adipose-derived stem cell suspension in a pre-filled syringe for autologous application

Proposed indication

Autoimmune diseases (rheumatoid arthritis and systemic lupus erythematosus)

EMA / CAT conclusion

The committee adopted on 26th January 2015 the following scientific recommendation.

On the basis that:

- the product is intended to be used for the treatment of autoimmune diseases (rheumatoid arthritis and systemic lupus erythematosus);

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- the product consists of human cells;

- the cells have been subject to substantial manipulation so that biological characteristics, physiological functions or structural properties relevant for the intended clinical use have been altered (but excluding the manipulations listed in Annex I to Regulation (EC) No 1394/2007);

- the cells are administered to human beings with a view to treating a disease through their pharmacological, immunological or metabolic action.

The EMA/CAT considers that the product falls within the definition of a somatic cell therapy medicinal product as provided in Article 2 (1) (a) of Regulation (EC) No 1394/2007.