EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

24 August 2018
EMA/576036/2018
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 *ex vivo* expanded regulatory T lymphocytes with the cell marker profile of $CD3^{+}$, $CD4^{+}$, $CD25^{high}$, $CD127^{-}$, $FoxP3^{+}$.

Brief description of the finished product

Suspension of autologous regulatory T lymphocytes.

Proposed indication

Treatment of Type 1 Diabetes Mellitus.

EMA / CAT conclusion

The procedure was finalised on 30 May 2016 for the following recommendation.

On the basis that the product:

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- consists of cells that have been subject to substantial manipulation so that biological characteristics, physiological functions or structural properties relevant for the intended clinical use have been altered;
- is administered to human beings with a view to treating a disease through the immunological action of its cells,

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