EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

28 May 2014
EMA/326383/2014
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)

Allogeneic engineered Chimeric Antigen Receptor (CAR+) T-cells

Brief description of the finished product

Suspension of cells

Proposed indication

Acute Lymphoblastic Leukemia and Chronic Lymphocytic Leukemia.

EMA/CAT conclusion

On the basis that:

- the product contains an active substance which contains a recombinant nucleic acid administered to human beings with a view to adding a genetic sequence;

- its therapeutic effect relates directly to the product of genetic expression of this sequence.

the EMA/CAT considers that the Product falls within the definition of a Gene Therapy Medicinal Product

7 Westferry Circus • Canary Wharf • London E14 4HB • United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7523 7051
E-mail info@ema.europa.eu **Website** www.ema.europa.eu