

24 November 2014 EMA/556370 /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)

In vitro derived platelets

Brief description of the finished product

Suspension of platelets

Proposed indication

Haemotology

EMA/CAT conclusion

On the basis that:

- Platelets are not considered cells for ATMP classification purposes as they are anucleate

the EMA/CAT considers that the Product does not fall within the definition of an Advanced Therapy Medicinal Product.

