16 March 2016
EMA/556344/2015
Procedure Management & Committees 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)

Adult stem cell population, prepared from human skeletal muscle, supposed to display myogenic differentiation abilities.

Brief description of the finished product

The product is a cell suspension of adult stem cell population, prepared from human skeletal muscle.

Proposed indication

The product would be indicated for the treatment of Duchenne Muscular Dystrophy (DMD)

EMA / CAT conclusion

The committee adopted on 30th March 2015 the following scientific recommendation.

On the basis that:

- The product consists of allogenic adult stem cell, isolated from human skeletal muscle that are cultivated *in-vitro*. The stem cells are therefore substantially manipulated.
- The Product is presented as having properties and administered to human beings with a view to regenerating, repairing and replacing a human tissue.

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

The EMA/CAT considers that the product falls within the definition of a Tissue Engineered Product as provided in Article 2 (1)(b) of Regulation (EC) No 1394/2007.