EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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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

Retinal pigment epithelium cells derived from human induced pluripotent stem cells

Brief description of the finished product

Suspension of Retinal pigment epithelium cells derived from human induced pluripotent stem cells in storage medium

Proposed indication

Treatment of retinal degenerative diseases associated with dystrophic or dysfunctional retinal pigment epithelium cells

EMA/CAT conclusion

On the basis that:

- the cells are substantially manipulated so that biological characteristics, physiological functions or structural properties relevant for the intended regeneration, repair or replacement are achieved, and

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

- the product is administered to human beings with a view to regenerating, and replacing a human tissue,

the EMA/CAT considers that the Product falls within the definition of a Tissue Engineered Product.