EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Press Office

Press release

CellSeed Europe Ltd. withdraws its marketing authorisation application for OraNera (autologous oral mucosal epithelial cells)

The European Medicines Agency has been formally notified by CellSeed Europe Ltd. of its decision to withdraw its application for a centralised marketing authorisation for the medicine OraNera (autologous oral mucosal epithelial cells), a living tissue equivalent consisting of two autologous oral mucosal epithelial cell-sheets. It was intended to be used for treatment of limbal stem cell deficiency (LSCD).

The application for the marketing authorisation for OraNera was submitted to the Agency on 1 June 2011. OraNera is an advanced therapy medicinal product (ATMP). At the time of the withdrawal, the medicine was under review by the Agency's Committee for Advanced Therapies (CAT) and the Committee for Medicinal Products for Human Use (CHMP).

In its official letter the company stated that it is withdrawing its application because, on the basis of the CAT's preliminary assessment, the Committee could not conclude on a positive benefit-risk balance. The company is not able to generate additional data required for a favourable opinion within the timeframe agreed in the centralised procedure.

More information about OraNera and the state of the scientific assessment at the time of withdrawal will be made available in a question-and-answer document. This document will be published on the Agency's website after the CHMP meeting of 18-21 March 2013.

Notes

1. This press release, together with all related documents, is available on the Agency's website.
2. Withdrawal of an application does not prejudice the possibility of a company making a new application at a later stage.
3. Advanced-therapy medicinal products are medicines for human use that are based on gene therapy, somatic-cell therapy or tissue engineering. They offer ground-breaking new opportunities for the treatment of disease and injury. More information can be found at:

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4. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

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