

CellSeed withdraws stem cell drug application

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CellSeed withdraws marketing application for OraNera

WITHDRAWN

Singapore: Europe's CellSeed has withdrawn its application for a centralized marketing authorization for the medicine OraNera (autologous oral mucosal epithelial cells), a living tissue equivalent consisting of two autologous oral mucosal epithelial cell-sheets from European Medicines Agency. 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.