



Dr Tomas Salmonson,
Chairman of CHMP
European Medicines Agency - EMA
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London, March 14, 2013

Withdrawal of OraNera (CAOMECS) Cultured Autologous Oral Mucosal Epithelial Cell-Sheet

Procedure Number- EMEA/H/C/002443

Dear Dr. Salmonson,

We would like to inform you of our decision to withdraw the application for Marketing Authorisation of the product OraNera (CAOMECS) Cultured Autologous Oral Mucosal Epithelial Cell-Sheet, a living tissue equivalent consisting of two autologous oral mucosal epithelial cell-sheets, each of which is transported in a single-use cell culture vessel – the UpCell™-insert, for the following intended indication: For the restoration of the ocular epithelial surface in patients with LSCD without stromal involvement.

This withdrawal is based on the following reasons:

- The CAT's preliminary assessment of the data provided thus far does not allow the Committee to draw the conclusion that a positive benefit-risk balance exists.
- The decision to withdraw was based on the view of the rapporteurs in their Day 150 assessment report that additional new data and analyses would be required in order to obtain a favourable opinion, which however the company is not able to generate within the timeframe allowed in the centralised procedure.

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There are currently no on-going clinical trials or a compassionate programme for this product. Accordingly, there are no anticipated consequences of this withdrawal.

CellSeed reserves the right to make further submissions at a date in the future in this or other therapeutic indication(s).

We agree for this letter to be published on the EMA website.

Yours sincerely,

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