

2 July 2018 EMA/457300/2018 EMEA/H/C/002522

## **Public statement**

## **MACI**

Expiry of the marketing authorisation in the European Union

The marketing authorisation for MACI (matrix applied characterised autologous cultured chondrocytes) expired on 1 July 2018 following the decision of the marketing authorisation holder, Vericel Denmark ApS, not to pursue the renewal of the marketing authorisation.

MACI was granted marketing authorisation in the European Union (EU) on 27 June 2013 as an implant used to repair cartilage defects in the knee joint.

The marketing authorisation for MACI had been suspended since 19 November 2014 due to the absence of an authorised manufacturing site for the finished product, active substance and batch release. The suspension had not been lifted prior to the expiry of the marketing authorisation.

The European Public Assessment Report (EPAR) for MACI will be updated accordingly to reflect the fact that the marketing authorisation is no longer valid.

