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**Cultured Autologous Oral Mucosal Epithelial Cell-Sheet: Interim Results of French Clinical Trial
Presented to World Cornea Congress, ASCRS-ASOA Symposium and Congress**

The interim results of the ongoing clinical trial on Cultured Autologous Oral Mucosal Epithelial Cell-Sheet was reported to the World Cornea Congress VI - American Society of Cataract and Refractive Surgery Symposium - American Society of Ophthalmic Administrators Congress - held in Boston, USA between April 7 and 14, 2010. The trial's principal investigator, Prof. Carole Burillon of University Lyon 1 (Department of Ophthalmology) delivered the presentation.

[Outline of Trial]

Clinical trial of Cultured Autologous Oral Mucosal Epithelial Cell-Sheet reported in the presentation:

- Institution: Les Hospices Civils De Lyon, France
- Period: September 2007 to June 2010 (proposed)
- Indication: Limbal stem cell deficiency (LSCD) with severe loss of vision
- Number of Cases: 25
- Main Evaluation Criteria: Reconstruction of epithelium, neovascularization on the epithelium, subjective awareness (improvement of visual acuity, dry eye, pain, photophobia), etc.

[Summary of Presentation]

- Cases whose interim results were presented: Out of the 25 cases included in the trial, 16 cases whose follow-up observation period as designated by the trial protocol (twelve months after the epithelial cell sheet transplantation) has been concluded.
- Points Made by Prof. Carole Burillon
 - The reconstruction of epithelium with sufficient functionality has been good.
 - Neovascularization on the epithelium (cause of functional disorder) after the epithelial cell sheet graft has decreased and symptoms have improved, compared to that before the graft.
 - In patients without damage to tissues other than the epithelium (corneal stroma and endothelium), improvement of visual acuity was observed.
 - Even in patients with damage to the stroma other than the epithelium, if the damaged stroma tissue was replaced with undamaged stroma using conventional donor corneal transplant, improvement of visual acuity was observed.

- In one case, a serious adverse event (corneal perforation) was observed six months after transplant, but this adverse event was unrelated to the epithelial cell sheet grafting.

Limbal Stem Cell Deficiency (LSCD) with severe loss of vision is the disorder indicated for treatment in this trial. LSCD is an intractable condition for which no established therapy has been found. Patients taking part in the trial are mainly those who have undergone conventional treatment in the past such as corneal transplant but who had insufficient improvement in their condition. According to Prof. Carole Burillon's presentation, symptoms have improved in 14 out of the 16 cases of this interim report compared to pre-transplantation. Deterioration was observed in only 2 cases (one case in which a serious adverse event occurred unrelated to the epithelial cell sheet transplant, and one case in which visual acuity deteriorated by one level but thought to be due to the condition of a part of eye other than the site of the transplantation). Although the trial's follow-up observation is still ongoing and no conclusion can be drawn, this presentation is a strong indication of the safety and efficacy of CellSeed's epithelial cell sheet for use in treating LSCD with severe loss of vision.

The follow-up observation of all 25 cases in this trial will be completed by the end of June 2010. Based on the final trial findings, CellSeed aims to submit before the end of 2010 an application for approval of the epithelial cell sheet for corneal regeneration (marketing licence) to the European Medicines Agency. CellSeed is making every effort in the preparation for this submission.

[Key Words]

Limbal Stem Cell Deficiency: Disorder arising from disease or injury, in which the stem cells in the epithelium (cells that regenerate tissue) are lost, halting the regeneration of the epithelium and leading to a variety of subjective symptoms relating to the epithelium (i.e. visual impairment, dry eye, pain, photophobia).

Epithelium: Part of the cornea formed of transparent tissue located on the outer surface of the cornea, which is exposed to the exterior of the body

Endothelium: Part of the cornea that is located on the opposite side of the cornea from the epithelium

Corneal Stroma: Transparent tissue sandwiched between the epithelium and endothelium, and consisting mainly of collagen

Corneal Perforation: Disease in which a perforation occurs in the cornea

(End of Release)