Confirmation Application for Allograft Cultured Corneal Epithelial Cell Sheets was Approved to be in Compliance With the Guidelines for New Biologics by MHLW (Ministry of Health, Labor and Welfare) in Japan

Date: June 5, 2009

We are on a mission to provide allograft cultured corneal epithelial cell sheets (development code: AMT-301) as a medical device to treat "Corneal epithelial stem cell deficiencies". In order to accomplish our mission, we have applied for confirmation application before IND to insure quality and safety for new biologics, including biological medical devices.

The final deliberation was held today, and confirmation application was found to be in compliance with the guidelines for new biologics including biological medical devices.

Deliberation passage:

Confirmation application was filed: March 28, 2008

1st deliberation council was held: April 2, 2009

Indicated diseases:

Corneal epithelial stem cell deficiencies (acute and chronic) focusing on Stevens Johnson Syndrome, Ocular Cicatrical Pemphigoid, and thermal/chemical erosion as primary diseases.

Corneal epithelial stem cell deficiencies are ocular surface diseases caused by primary diseases above in which corneal epithelial cells lose their functions. For severe cases, there was no effective therapy and patients eventually became blind. AMT-301 is made by culturing epithelial cells of donated corneas from the Eye Bank on donated human amniotic membranes. Transplantation of AMT-301 to the corneal surface limits disease progression, gives the patient better eye sight, and can be used for acute stage patients, even though surgical procedures were contraindicated in acute stage patients in the past. AMT-301 was designated as an Orphan Medical Device by MHLW on June 11, 2008.

Clinical research for the treatment utilizing cultured corneal epithelial cell sheets have been performed not only by Kyoto prefectural Medical University Ophthalmology Department led by the original inventor of this technology, Prof. Shigeru Kinoshita, but also by several affiliated university hospitals since 1999. Many patients have been saved from blindness and some have resumed their places in society. It is our hope that AMT-301 will help as many patients as possible to regain their sight.

ArBlast is aiming to start Phase 3 clinical study in 4 facilities this year to gain official approval from MHLW.

If you have any questions, please contact:
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