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News Release

February 26, 2007

Astellas Receives a Positive CHMP Opinion for EU Marketing Authorisation for FK506 Modified Release as a Once-Daily Immunosuppressant in Organ Transplantation

Tokyo, Japan February 26, 2007 - Astellas Pharma Inc. (Headquarters: Tokyo, President and CEO: Masafumi Nogimori) announced today that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMEA) has adopted a positive opinion recommending marketing approval of the once-daily immunosuppressant FK506 Modified Release formulation (generic name: tacrolimus) for the prevention of rejection in organ transplantation.

FK506 Modified Release is a once-daily formulation of Astellas' twice-daily formulation of Prograf® (tacrolimus), a leading immunosuppressive agent marketed in over 70 countries around the world for prevention of organ rejection in kidney, liver or heart transplant recipients.

The availability of a once-daily formulation dosing regimen may have the potential to increase patient compliance, and hence long-term efficacy of immunosuppression, representing a step forward in the management of transplant patients. This formulation is expected to be at least as safe as the conventional formulation.

The CHMP based its positive opinion on its review of the comprehensive data package for FK506 Modified Release, which characterised its efficacy and safety profile. The indication for FK506 Modified Release is: "Prophylaxis of transplant rejection in adult kidney or liver allograft recipients. Treatment of allograft rejection resistant to treatment with other immunosuppressive medicinal products in adult patients".

Following the CHMP's positive opinion, the application will be reviewed by the European Commission which has the authority to grant a marketing authorisation for the European Union. This Commission Decision is anticipated after approximately two and half months.

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