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News Release

September 19, 2007

Astellas Submitted a Response to the FDA Action Letter for FK506 Modified Release Formulation for Kidney Transplantation

Japan, September 19, 2007 - Astellas Pharma Inc. (headquarters: Tokyo, president and CEO: Masafumi Nogimori, "Astellas") today announced that its US subsidiary, Astellas Pharma US, Inc. (headquarters: Deerfield, IL, "Astellas US") submitted a response to the action letter from the U.S. Food and Drug Administration (FDA) for the once daily immunosuppressant FK506 Modified Release, known in the US as "extended-release", formulation (generic name: tacrolimus) for the prophylaxis of organ rejection in kidney transplant patients.

In December 2005, Astellas US submitted a New Drug Application (NDA) for the FK506 Modified Release formulation, seeking approval for use in the prophylaxis for organ rejection in kidney, liver and heart transplant patients. Three action letters were received on January 19, 2007; each addresses one of the three targeted indications as follows:

- for prophylaxis of organ rejection in kidney transplant patients : Approvable
- for prophylaxis of organ rejection in liver transplant patients : Approvable
- for prophylaxis of organ rejection in heart transplant patients : Not approvable

Astellas US submitted a response to the action letter for prophylaxis of organ rejection in liver transplant patients in July 2007 and is internally examining the response strategy for the prophylaxis of organ rejection in heart transplant patients.

FK506 Modified Release formulation is a once-daily formulation of Astellas' Prograf® (tacrolimus, twice-daily formulation), an immunosuppressive agent. Most transplant patients are prescribed a multitude of medications that require multiple dosing at various times throughout the day. FK506 Modified Release formulation, with its more convenient once-daily dosing may provide an alternative to twice daily Prograf.

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