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News Release

March 14, 2008

Astellas Receives an Approvable Letter for Their Immunosuppressant FK506 Modified Release Formulation in the U.S.

Japan, March 14, 2008 - Astellas Pharma Inc. (headquarters: Tokyo, President and CEO: Masafumi Nogimori, "Astellas") today announced that its U.S. subsidiary, Astellas Pharma US, Inc. (headquarters: Deerfield, IL, "Astellas Pharma US") received an approvable letter from the U.S. Food and Drug Administration (FDA) for a New Drug Application (NDA) regarding its once-daily immunosuppressant FK506 Modified Release formulation (generic name: tacrolimus) for the prophylaxis of organ rejection in patients receiving allogeneic kidney transplants on March 13, 2008 (local time).

In December 2005, Astellas Pharma US submitted an NDA for FK506 Modified Release formulation, seeking approval for use in the prophylaxis of organ rejection in patients receiving allogeneic kidney, liver and heart transplants. The FDA issued approvable letters for the use in kidney and liver recipients and a not approvable letter for the use in heart recipients on January 19, 2007. Astellas Pharma US submitted a response to the action letter for the use in kidney recipients in September 2007 and received an approvable letter from the FDA on March 13, 2008. Astellas is internally examining the future strategy and will continue to work closely with the FDA to better understand the issues raised. In January 2008, Astellas Pharma US was notified by the FDA that the review of the application for use in liver transplant recipients will be extended. Astellas is internally examining the response strategy for the use in heart recipients.

FK506 Modified Release formulation is a once-daily formulation of Astellas's immunosuppressant Prograf® (tacrolimus capsule) twice-a-day.

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