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News Release

May 7, 2008

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

Japan, May 7, 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 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 liver transplants on April 30, 2008 (local time).

In December 2005, Astellas 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. FDA issued an approvable letter for the use in liver transplantation in January 2007. Astellas US submitted a response to the action letter for the use in liver transplantation in July 2007 and received an approvable letter from the FDA on April 30, 2008. Astellas is internally examining the future strategy and will continue to work closely with the FDA to better understand the issues raised. Astellas US also received an approvable letter for the use in kidney transplantation in January 2007 and in March 2008 and a not approvable letter for the use in heart transplantation in January 2007 from the FDA. Astellas is internally examining the future strategy for these indications.

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

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