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News Release

January 23, 2007

Astellas Receives an Action Letter from FDA for NDA of FK506 MR in the U.S.

Japan, January 23, 2007 - Astellas Pharma Inc. (headquarters: Tokyo, president and CEO: Masafumi Nogimori) today announced that its US subsidiary, Astellas Pharma US, Inc.(headquarters: Deerfield, IL) received an action letter from the U.S. Food and Drug Administration (FDA) for the New Drug Application (NDA) regarding its once daily immunosuppressant FK506 Modified Release formulation (generic name: tacrolimus) on January 19, 2007 (local time).

The action letter addresses each of the three target indications, the prophylaxis for organ rejection in kidney, liver and heart transplant patients 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

In their letter, the FDA raises additional issues and questions for each of the three indications, Astellas is internally reviewing the comments outlined in the action letters and is working with the FDA to address any issues they have raised to secure approval of FK506 MR.

Tacrolimus is an immunosuppressant invented by Astellas. Its twice a daily formulation, Prograf® has been marketed about 70 countries around the world. The FK506 modified release formulation is a modified release version of Prograf that can be administered once a day.

The NDA of FK506 MR was submitted to the FDA in the U.S. in December 2005. Application for regulatory approval has also been filed in Japan and Europe.

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