

May 30, 2006

Application for the immunosuppressant FK506 Modified Release Formulation in Japan

Japan, May 30, 2006 - Astellas Pharma Inc. (“Astellas”; headquarters: Tokyo; President and CEO: Toichi Takenaka) today announced that it has submitted an application for the market authorization for the immunosuppressant FK506 Modified Release Formulation (generic name: tacrolimus) to the Pharmaceuticals and Medical Devices Agency (PMDA) with the proposed indication of “suppression of organ rejection in organ transplantation” and “suppression of graft rejection and GVHD in bone marrow transplantation” on May 29, 2006 in Japan.

Tacrolimus is an immunosuppressant discovered and developed by Astellas and is marketed as an immunosuppressant for organ transplantation under the brand name Prograf® in more than 70 countries. Since FK506 Modified Release Formulation is a once-daily oral formulation of tacrolimus, patients’ compliance is expected to be improved compared to twice a day with the conventional formulation. The FK506 modified release formulation is therefore expected long term graft protective effect. In addition, this formulation is expected to be at least as safe as the conventional formulation since peak blood concentrations can be controlled at lower or even levels.

As far as FK506 Modified Release Formulation is concerned, Astellas submitted a New Drug Application (NDA) in the US and a Marketing Authorization Application (MAA) in Europe, respectively, prior to the Japanese application.

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Contacts for inquiries or additional information
Astellas Pharma Inc. Corporate Communications Tel: +81-3-3244-3201 Fax: +81-3-5201-7473 http://www.astellas.com