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News Release

July 17, 2008

Astellas Receives a Japanese Marketing Approval for the Immunosuppressant Graceptor®

Japan, July 17, 2008 - Astellas Pharma Inc. (headquarters: Tokyo, president and CEO: Masafumi Nogimori, "Astellas") today announced that it has received a Japanese marketing approval for the immunosuppressant Graceptor® Capsules 0.5mg, 1mg, 5mg (generic name: tacrolimus hydrate) (FK506 Modified Release Formulation) for "suppression of organ rejection" and "suppression of graft rejection and GVHD in bone marrow transplantation." A New Drug Application had been submitted in May 2006.

Graceptor is a once-daily modified release formulation of Astellas's Prograf® (tacrolimus, twice-daily formulation). Tacrolimus works as an immunosuppressant by inhibiting production of cytokine including differentiation/growth factor secreted from T-cell, interleukin-2 and interferon-gamma. Once-daily administration of Graceptor is expected to improve long-term compliance with its more convenient once-daily dosing option, and may have the potential to reduce the incidence of graft loss. The European Committee has granted an European Marketing Authorisation for a once-daily formulation of Prograf in April 2007. It has been available with the brand name Advagraf® throughout Europe starting with the UK and Germany since June 2007. It is currently marketed in 18 countries worldwide including Canada.

Astellas expects to provide a new option for transplant medication with the new lineup for Prograf family.

The launch timing will be announced after it appears in the NHI Drug Price List.

Details of approval are as follows:

Date of marketing approval:	July 16, 2008
Brand name:	Graceptor® Capsules 0.5mg, 1mg and 5 mg
Generic name:	tacrolimus hydrate
Classification:	Immunosuppressant
Indication:	Suppression of organ rejection in the following organ transplantation Kidney transplantation, liver transplantation, heart transplantation, lung transplantation, pancreas transplantation Suppression of graft rejection and GVHD in bone marrow transplantation
Approval holder:	Astellas Pharma Inc.

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