

October 27, 2008

Astellas Launches the Immunosuppressant Graceptor[®] in Japan

Japan, October 27, 2008 - Astellas Pharma Inc. (headquarters: Tokyo, president and CEO: Masafumi Nogimori, “Astellas”) today announced that its immunosuppressant Graceptor[®] Capsules 0.5mg, 1mg, 5mg (generic name: tacrolimus hydrate) will become available in Japan on October 28, 2008 with the indication of “suppression of organ rejection” and “suppression of graft rejection and graft versus host disease (GVHD) in bone marrow transplantation.”

Graceptor is a once-daily modified release formulation of Astellas’s Prograf[®] (tacrolimus, twice-daily formulation). Tacrolimus works as an immunosuppressant by inhibiting activation of T-cell.

Graceptor maintains its efficacy and safety at the similar level with the existing drug, Prograf. Once-daily administration possibly contributes to reduce physical and mental stress for patients who need to take several different medications in a long-term. It is expected to improve compliance with its more convenient once-daily dosing option, and may lead to improve long term outcomes of transplantation.

Once-daily formulation of Prograf has been available with the brand name Advagraf[®] in 19 countries worldwide including Europe. Astellas expects to provide a new option for transplant medication with the new lineup for Prograf family.

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 graft versus host disease (GVHD) in bone marrow transplantation

Dosage and administration:

[Kidney transplantation] Usually, a dose of 0.15 - 0.20 mg/kg as tacrolimus is orally administered, once daily from the morning 2 days before transplantation. The dosage may be adjusted thereafter depending on the patient's symptoms.

[Liver transplantation] Usually, in the early postoperative period, a dose of 0.10 - 0.15 mg/kg as tacrolimus, is orally administered once daily in the morning. The dosage may be adjusted thereafter depending on the patient's symptoms.

[In case of converting from oral Prograf to this product (in kidney transplantation, liver transplantation, heart transplantation, lung transplantation, pancreas transplantation, or bone marrow transplantation)] In case of converting from oral Prograf to this product, the usual dosage for oral use is the same as the daily dose of oral Prograf, once daily in the morning.

Approval holder: Astellas Pharma Inc.

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Contacts for inquiries or additional information
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