

October 16, 2009

Approval of Additional Indications for the immunosuppressant Prograf® for Myasthenia Gravis in Japan

Tokyo, Japan, October 16, 2009 - Astellas Pharma Inc. (“Astellas”; headquarters: Tokyo; President and CEO: Masafumi Nogimori) today announced that it was granted approval for “myasthenia gravis” as additional indication for the immunosuppressant Prograf® (generic name: tacrolimus hydrate), submitted an sNDA to the Pharmaceuticals and Medical Devices Agency (PMDA) in September 2008 in Japan. Prograf already had been approved for “myasthenia gravis in a case where the effect of steroids is insufficient or administration of steroids is difficult because of adverse reactions in the treatment after thymectomy” since September 2000. Prograf has now been approved for “myasthenia gravis” covering such not included in past indication.

Myasthenia gravis is an autoimmune disorder, characterized by muscle weakness and fatigability (due to the disruption on the junctions between nerves and muscles). It is suggested as the cause of myasthenia gravis that anti-acetylcholine receptor (AChR) antibodies produced by the immune system attack AChR and disrupt transmission of the neuromuscular junction. The production of anti-AChR antibodies is activated by stimulation with inflammatory cytokines from activated T-lymphocytes. Prograf is expected to relieve the symptoms of myasthenia gravis through reducing the production of antibodies from B-lymphocytes by suppressing production of inflammatory cytokines from activated T-lymphocytes.

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 80 countries/areas. In Japan, Prograf was also approved for bone marrow transplantation, rheumatoid arthritis, lupus nephritis and ulcerative colitis. Additionally, a once-daily oral formulation of tacrolimus is available in 29 countries/areas, including Japan under the brand name Graceptor® and Europe under the brand name Advagraf®.

Astellas believes this approval will further contribute to the medical treatment of myasthenia gravis in Japan.

#####

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