

September 30, 2008

Astellas Submits an sNDA for the immunosuppressant Prograf[®] for Myasthenia Gravis in Japan

Japan, September 30, 2008 - Astellas Pharma Inc. (“Astellas”; headquarters: Tokyo; President and CEO: Masafumi Nogimori) today announced that it has submitted an sNDA to the Pharmaceuticals and Medical Devices Agency (PMDA) for the immunosuppressant Prograf[®] (generic name: tacrolimus) for myasthenia gravis on September 29, 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. Astellas has submitted an sNDA in order to extend its indication covering all myasthenia gravis.

Myasthenia gravis is an autoimmune disorder, characterized by muscle weakness and fatigability (due to the disruption on the junctions between nerves and muscles). Symptoms tend to worsen with muscle activity and improve with rest. 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 approximately 80 countries. In Japan, Prograf was approved for additional indications of bone marrow transplantation, systemic myasthenia gravis, rheumatoid arthritis and lupus nephritis. Moreover, Astellas received a Japanese marketing approval for the immunosuppressant Graceptor[®], a once-daily oral formulation of tacrolimus, in July 2008 and is now under the preparation phase for the launch. In addition, tacrolimus ointment for the treatment of atopic dermatitis has been marketed in approximately 60 countries worldwide under the brand name Protopic[®].

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