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News Release

June 23, 2008

Submit an sNDA for the immunosuppressant Prograf® for Ulcerative Colitis in Japan

Japan, June 23, 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 ulcerative colitis on June 20, 2008 in Japan.

Ulcerative colitis is a chronic inflammation disease in which the large intestine becomes eroded and ulcerated. Common symptoms are persistent or repetitive mucous and bloody stool. Although many theories exist regarding the cause of ulcerative colitis, none has been proven. Currently, some studies indicated that immunological abnormality at the part of intestinal mucosa relates to the cause of ulcerative colitis. Prograf is expected to relieve the symptoms of ulcerative colitis through reducing the inflammation in the large intestine 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. In Japan, Prograf was approved for bone marrow transplantation, systemic myasthenia gravis, rheumatoid arthritis, and lupus nephritis; moreover, Astellas submitted an application for FK506 Modified Release Formulation, a once-daily oral formulation of tacrolimus. In addition, tacrolimus ointment under the brand name Protopic® for the treatment of atopic dermatitis has been marketed in approximately 60 countries worldwide.

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