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News Release

July 7, 2009

Approval of Additional Indications for the immunosuppressant Prograf®

for Ulcerative Colitis in Japan

Tokyo, Japan, July 7, 2009 - Astellas Pharma Inc. ("Astellas"; headquarters: Tokyo; President and CEO: Masafumi Nogimori) today announced that it was granted approval for moderately/severely refractory (steroid resistance and steroid dependency) ulcerative colitis as additional indication for the immunosuppressant Prograf® (generic name: tacrolimus hydrate), submitted an sNDA to the Pharmaceuticals and Medical Devices Agency (PMDA) in June 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/areas. In Japan, Prograf was also approved for bone marrow transplantation, systemic myasthenia gravis, rheumatoid arthritis, and lupus nephritis; moreover, Astellas submitted an application for myasthenia gravis (all). Additionally, a once-daily oral formulation of tacrolimus is available in 25 countries worldwide, including Japan under the brand name Graceptor® and Europe under the brand name Advagraf®.

Astellas believes this approval will contribute to the medical treatment of ulcerative colitis in Japan.

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