

Astellas Pharma Inc.: Approval of Prograf[®] capsules in Japan for the additional indication of interstitial pneumonia associated with polymyositis /dermatomyositis

TOKYO, June 14, 2013 - [Astellas Pharma Inc.](http://www.astellas.com) (“Astellas”; Tokyo:4503; President and CEO: Yoshihiko Hatanaka) announced today that it has been granted approval in Japan for the additional indication of interstitial pneumonia associated with polymyositis/dermatomyositis for Prograf[®] capsules 0.5mg, 1.0mg (generic name: tacrolimus hydrate).

Tacrolimus is an immunosuppressant discovered and developed by Astellas. The capsule formulation of tacrolimus is marketed as an immunosuppressant for organ transplantation etc. under the brand name “Prograf[®]” etc. in 99* countries/areas. In Japan, Prograf was also approved for myasthenia gravis, rheumatoid arthritis, lupus nephritis and ulcerative colitis.

The additional indication, interstitial pneumonia associated with polymyositis/dermatomyositis, is an orphan disease that affects approximately 10,000 patients in Japan. Investigator-initiated clinical trial** using tacrolimus in these patients, adopted as part of clinical research promotion program by Health Labour Sciences Research Grant from the Ministry of Health, Labour and Welfare, began in August 2007 and an application for approval based on the results was submitted in September 2012. “Orphan Drug Designation” was granted by the Ministry of Health, Labor and Welfare prior to the submission.

Astellas expects that this approval will offer a new treatment option for patients who have not been provided sufficient effects with the existing drug, suffering from interstitial pneumonia associated with polymyositis/dermatomyositis.

The impact of this approval on Astellas’ financial forecasts for the current fiscal year (from April 1, 2013 to March 31, 2014) will not be material.

* As of March 2013

** The Pharmaceutical Affairs Law was amended in 2003 to allow physicians themselves to design and plan clinical trials, submit trial protocols and conduct trials in the same manner as pharmaceutical companies etc. Trials prepared and directly managed by physicians are known as investigator-initiated trials.

<http://www.jmacct.med.or.jp/en/what-we-do/investigator.html>

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For inquiries or additional information

Astellas Pharma Inc.

Corporate Communications

TEL: +81-3-3244-3201, FAX:+81-3-5201-7473

<http://www.astellas.com/en>