Press Release

Astellas Submits Application for Approval of Peficitinib for Rheumatoid Arthritis (Including Prevention of Structural Joint Damage) in Patients Who Have an Inadequate Response to Conventional Therapies in Japan

TOKYO, May 31, 2018 - Astellas Pharma Inc. (President and CEO: Kenji Yasukawa, Ph.D., "Astellas") today announced that it has submitted an application for marketing approval of peficitinib hydrobromide (generic name; development code: ASP015K, "peficitinib") for the treatment of rheumatoid arthritis (including prevention of structural joint damage) in patients who have an inadequate response to conventional therapy in Japan.

Peficitinib, an orally available Janus kinase (JAK) inhibitor discovered by Astellas, suppresses activation and proliferation of inflammatory cells involved in synovial inflammation and joint destruction in rheumatoid arthritis patients through inhibition of various inflammatory cytokine signaling pathways.

The submission is based mainly on the results obtained from two Phase 3 trials (RAJ3 and RAJ4) of peficitinib in rheumatoid arthritis patients who had an inadequate response to conventional therapy. The primary endpoint of RAJ3*[1] was "ACR*[2]20 response rate at Week 12 (percentage of patients with improvement of at least 20% in various rheumatoid arthritis endpoints)." The co-primary endpoints of RAJ4*[3] trial were "ACR20 response rate at Week 12" and "suppression of joint destruction at Week 28 (change in mTSS*[4] from baseline)." Both trials demonstrated superiority over placebo and met the primary endpoints. The safety analysis of these trial appears consistent with the safety profile of peficitinib in previous clinical trials and no new safety signals were observed. It is also planned to present them in detail at a future medical conference.

According to epidemiological data, the number of rheumatoid arthritis patients is approximately 0.7 to 0.8 million in Japan. With this submission, Astellas expects to contribute to treatments of rheumatoid arthritis patients with an inadequate response to conventional therapy, such as Methotrexate (MTX) and disease-modifying antirheumatic drugs (DMARDs)*[5], by providing peficitinib as a new therapeutic option.

Further, Astellas intends to discuss the data with the regulatory authorities in Asian countries to support filing new drug application.

(1) RAJ3: The trial is a multinational, randomized, placebo-controlled, double-blind study. It included around 500 rheumatoid arthritis patients with an inadequate response to disease-modifying antirheumatic drugs (DMARDs)*5 at medical institutions in Japan, Korea and Taiwan. The efficacy of peficitinib (100 mg/day or 150 mg/day), in combination with DMARDs and without DMARDs, was evaluated versus placebo regarding ACR*220 response rate at Week 12 as the primary endpoint.

(2) ACR: Evaluation criterion proposed by American College of Rheumatology (ACR) for measuring efficacy of antirheumatic therapy. For example, an improvement of at least 20% in specific endpoints for RA is expressed as ACR20.

(3) RAJ4: The trial is a randomized, placebo-controlled, double-blind study. It included around 500 rheumatoid arthritis patients with an inadequate response to methotrexate (MTX) at medical institutions in Japan. The efficacy of peficitinib (100 mg/day or 150 mg/day) in combination with MTX was evaluated versus placebo regarding the co-primary endpoints of ACR20 response rate at Week 12 and suppression of joint destruction (change in mTSS*4 from baseline) at Week 28.

(4) mTSS (modified Total Sharp Score): A methodology widely used for evaluating temporal changes in hand and foot joints in rheumatoid arthritis. It is used to evaluate the degree of joint destruction in rheumatoid arthritis patients using X-ray images.

(5) DMARDs (disease modifying antirheumatic drugs): General name for existing therapies that control RA activity by modifying the disorder of the immune system that causes rheumatoid arthritis, but do not have an inflammation suppressing action.

About Astellas

Astellas Pharma Inc., based in Tokyo, Japan, is a company dedicated to improving the health of people around the world through the provision of innovative and reliable pharmaceutical products. For more information, please visit our website at https://www.astellas.com/en

Cautionary Notes

In this press release, statements made with respect to current plans, estimates, strategies and beliefs and other statements that are not historical facts are forward-looking statements about the future performance of Astellas. These statements are based on management's current assumptions and beliefs in light of the information currently available to it and involve known and unknown risks and uncertainties. A number of factors could cause actual results to differ materially from those discussed in the forward-looking statements. Such factors include, but are not limited to: (i) changes in general economic conditions and in laws and regulations, relating to pharmaceutical markets, (ii) currency exchange rate fluctuations, (iii) delays in new product launches, (iv) the inability of Astellas to market existing and new products effectively, (v) the inability of Astellas to continue to effectively research and develop products accepted by customers in highly competitive markets, and (vi) infringements of Astellas' intellectual property rights by third parties.

Information about pharmaceutical products (including products currently in development) which is included in this press release is not intended to constitute an advertisement or medical advice.

###

Contacts for inquiries or additional information:

Astellas Pharma Inc.
Corporate Communications
TEL: +81-3-3244-3201 FAX: +81-3-5201-7473