Press Release

Astellas Announce Top-Line Results for Two Phase 3 Trials of Peficitinib in Rheumatoid Arthritis Patients with Inadequate Response to Existing Therapy

Tokyo, February 8, 2018 - Astellas Pharma Inc. (President and CEO: Yoshihiko Hatanaka, "Astellas") announced today that the results of two Phase 3 trials (RAJ3 and RAJ4 trials) on Peficitinib hydrobromide (generic name; development code: ASP015K, "Peficitinib"), an oral JAK inhibitor developed by Astellas, in rheumatoid arthritis patients with an inadequate response to existing therapy, demonstrated superiority over placebo regarding the two traials' primary endpoints. The primary endpoint of RAJ3, "ACR*[1]20 response rate at Week 12 (percentage of patients with improvement of at least 20% in various rheumatoid arthritis endpoints)" was met. The co-primary endpoints of RAJ4 trial, "ACR20 response rate at Week 12" and "suppression of joint destruction at Week 28 (change in mTSS*[2] from baseline)" were also met. The safety analysis of these trial appears consistent with the safety profile of Peficitinib in previous clinical trials and no new saftey signal was observed.

1) RAJ3 is a multinational, randomized, placebo-controlled, double-blind study. It included around 500 rheumatoid arthritis (RA) patients with an inadequate response to disease-modifying antirheumatic drugs (DMARDs)*[3] 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 ACR20 response rate at Week 12 as the primary endpoint.

2) RAJ4 is a randomized, placebo-controlled, double-blind study. It included around 500 RA 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*[2] from baseline) at Week 28.

Based on the results of these trials, Astellas intends to discuss the data with the regulatory authorities in Japan and other Asian countries to support filing NDA. It is also planned to present them in detail at a future medical conference.

Astellas expects to provide a new therapeutic option to patients with an inadequate response to existing therapy at an early date by pursuing the development of peficitinib.

(1) 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 rheumatoid arthritis is expressed as ACR20.

(2) 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 RA patients using X-ray images.

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

Further details: http://www.rheuma-net.or.jp/rheuma/rm400/library/pdf/guideline5to8.pdf

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. We focus on Urology, Oncology, Immunology, Nephrology and Neuroscience as prioritized therapeutic areas while advancing new therapeutic areas and discovery research leveraging new technologies/modalities. We are also creating new value by combining internal capabilities and external expertise in the medical/healthcare business. Astellas is on the forefront of healthcare change to turn innovative science into value for patients. 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.

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