Press Release

Oral JAK Inhibitor Smyraf® Tablets Approved in Japan for the Treatment of Rheumatoid Arthritis (including prevention of structural joint damage) in Patients Who Have an Inadequate Response to Conventional Therapies

TOKYO, March 26, 2019 - Astellas Pharma Inc. (TSE: 4503, President and CEO: Kenji Yasukawa, Ph.D., "Astellas") today announced that Smyraf® 50 mg and 100 mg Tablets (generic name: peficitinib hydrobromide), an oral Janus kinase (JAK) inhibitor, received manufacturing and marketing approval in Japan for the treatment of rheumatoid arthritis (including prevention of structural joint damage) in patients who have an inadequate response to conventional therapies.

Smyraf®, which was discovered by Astellas, suppresses activation and proliferation of inflammatory cells involved in synovial inflammation and joint destruction in rheumatoid arthritis patients by inhibiting various inflammatory cytokine signaling pathways.

The approval is based mainly on the results from two Phase 3 trials (RAJ3*[1] and RAJ4*[2]) of peficitinib in rheumatoid arthritis patients who had an inadequate response to conventional therapy. 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.

The number of rheumatoid arthritis patients in Japan is estimated to be approximately 0.6 to 1 million*[3]. By providing Smyraf® as a new therapeutic option, Astellas will contribute to treatment of rheumatoid arthritis patients with an inadequate response to conventional therapy such as Methotrexate (MTX) and disease-modifying antirheumatic drugs (DMARDs)*[4].

Important Product Information

Trade name	Smyraf® 50 mg and 100 mg
Generic name	peficitinib hydrobromide
Indication	rheumatoid arthritis (including prevention of structural joint damage) in patients who have an inadequate response to conventional therapies
Dosage and administration	For adults, the usual dosage is 150 mg as peficitinib orally administered once daily after a meal. The dose can be 100 mg once daily depending on the patient's condition.
Date of approval	March 26, 2019

(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) 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*[5]20 response rate at Week 12 as the primary endpoint.

(2) 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*[6] from baseline) at Week 28.

(3) KOUSEI KAGAKU SINGIKAI SIPPEI TAISAKU BUKAI rheumatoid arthritis committee report (November 2018), page4

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

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

(6) 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.

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.

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Contacts for inquiries or additional information:

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