Press Release

Launch of Smyraf® Tablets

- Provides a new therapeutic option for rheumatoid arthritis in patients who have an inadequate response to conventional therapies -

TOKYO, July 10, 2019 - Astellas Pharma Inc. (TSE: 4503, President and CEO: Kenji Yasukawa, Ph.D., "Astellas") today announced the launch of the Smyraf® 50 mg and 100 mg Tablets (generic name: peficitinib hydrobromide), an oral Janus kinase (JAK) inhibitor, 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 number of rheumatoid arthritis patients in Japan is estimated to be approximately 0.6 to 1.0 million*[1]. Currently, disease-modifying antirheumatic drugs (DMARDs)*[2] including Methotrexate (MTX) and biologics, are used to treat rheumatoid arthritis. 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 DMARDs.

Astellas reflected the impact from this launch in its financial forecasts of the current fiscal year ending March 31, 2020.

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
Date of NHI drug price listing	May 22, 2019
Date of Launch	July 10, 2019

Product photo

(1) KOUSEI KAGAKU SINGIKAI SIPPEI TAISAKU BUKAI rheumatoid arthritis committee report (November 2018), page 4

(2) 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.

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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