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ASIA EDITION

AbbVie gets the first global regulatory approval of SKYRIZI in Japan

March 27, 2019 | News

SKYRIZI is part of a collaboration between Boehringer Ingelheim and AbbVie



AbbVie, a research-based global biopharmaceutical company, has announced that the Japanese Ministry of Health, Labour and Welfare (MHLW) has approved SKYRIZI (risankizumab), an interleukin-23 (IL-23) inhibitor, for the treatment of plaque psoriasis, generalized pustular psoriasis, erythrodermic psoriasis and psoriatic arthritis in adult patients who have an inadequate response to conventional therapies. This approval marks the first country approval in the world for SKYRIZI.

"With this first global approval of SKYRIZI, we are excited to bring a new treatment option to people living with psoriatic disease in Japan," said Michael Severino, M.D., vice chairman and president, AbbVie. "SKYRIZI has the potential to improve the signs and symptoms of these chronic, immune-mediated diseases. We look forward to continuing to work with regulatory authorities to make this treatment available to more patients worldwide."

Psoriasis is a chronic, non-communicable inflammatory condition characterized by inflamed, scaly patches that typically causes people to experience itchiness, burning and stinging. Psoriasis is linked to several associated conditions, and in Japan, as many as 15 percent of individuals with psoriasis also develop psoriatic arthritis, a chronic, inflammatory disease that leads to irreversible joint deformations and disability. Worldwide, as many as 30 percent of people living with psoriasis may develop psoriatic arthritis.

"Advances in our understanding of psoriatic disease have brought us to an era where clear skin is a realistic treatment goal," said Mamitaro Ohtsuki, M.D., Ph.D., Chairman and Professor, Department of Dermatology, Jichi Medical University. "SKYRIZI has the potential to help psoriasis patients achieve high rates of skin clearance bringing them closer to reaching long-term treatment goals with every 12-week dosing."

The approval is based on efficacy and safety data from Phase 2 and Phase 3 clinical trials, sustaIMM, ultIMMa-1 and IMMspire, evaluating SKYRIZI in Japanese patients with plaque psoriasis, generalized pustular psoriasis and erythrodermic psoriasis, as well as a global Phase 2 study in patients with active psoriatic arthritis.

SKYRIZI is part of a collaboration between Boehringer Ingelheim and AbbVie, with AbbVie leading development and commercialization of SKYRIZI globally.

The European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion for SKYRIZI for treatment of moderate to severe plaque psoriasis in adult patients who are candidates for systemic therapy in February 2019. SKYRIZI is currently under review with the U.S. Food and Drug Administration (FDA) and a regulatory decision is anticipated in the first half of 2019.

SKYRIZI is approved for the treatment of psoriasis vulgaris, psoriatic arthritis, generalized pustular psoriasis, or erythrodermic psoriasis in adult patients who responded inadequately to conventional therapies.