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Japanese nod for Janssen psoriatic arthritis drug

September 24, 2013 | Regulatory | By BioSpectrum Bureau



Singapore: European Commission has approved Janssen-Cilag International's Stelara (ustekinumab), as a stand-alone drug or in combination with methotrexate, for the treatment of active psoriatic arthritis in adult patients when the response to previous non-biological disease-modifying anti-rheumatic drug (DMARD) therapy has been inadequate.

The decision from the European Commission follows a positive opinion recommending the use of Stelara from the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) in July 2013.

Stelara is the first in a new class of biologics now available for patients living with active psoriatic arthritis, a chronic autoimmune disease characterized by joint swelling and tenderness, periarticular tissue inflammation (enthesitis, inflammation of the site where ligaments or tendons insert into the bones, and dactylitis, inflammation of an entire digit, eg, finger or toe, often called sausage digit), as well as psoriasis. The disease affects approximately 4.2 million people across Europe, and there is currently no cure.

"The European Commission approval of Stelara for the treatment of active psoriatic arthritis brings an important new therapeutic option to patients and marks the first treatment approved for this devastating and complex disease since the introduction of anti-tumor necrosis factor (TNF)-alpha agents," said Dr Jerome A Boscia, VP and head, Immunology Development, Janssen Research & Development.

"Data from the phase III clinical program, one of the largest conducted for a biologic to date in psoriatic arthritis, showed Stelara effective in improving symptoms and signs of active psoriatic arthritis in anti-TNF-alpha naÃ?Æ?Ã?Â¨ve and experienced patients. We believe Stelara will play a critically important role in the treatment of this chronic disease moving forward."