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ASIA EDITION

Pfizer receives Breakthrough Therapy designation for inhibitor drug

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Breakthrough Therapy status provides for more intensive guidance from the FDA on development, the involvement of more senior agency personnel and a rolling review of the marketing application.



Singapore - Pfizer announced its investigational oral Janus kinase 3 (JAK3) inhibitor PF-06651600 received Breakthrough Therapy designation from the U.S. Food and Drug Administration (FDA) for the treatment of patients with alopecia areata, a chronic autoimmune skin disease that causes hair loss on the scalp, face, or body.

The Breakthrough Therapy designation for alopecia areata was supported by positive results from a Phase 2 study, which will be presented during the late-breaking news session at the 27th European Academy of Dermatology and Venerology (EADV) Congress in Paris on September 15, 2018. Currently, there are no FDA-approved treatments for alopecia areata, which impacts millions of people worldwide and is often associated with profound psychological consequences.

“We are encouraged by this Breakthrough Therapy designation as it underscores the potential of our JAK3 inhibitor to address a critical unmet need,” said Michael Corbo, Chief Development Officer, Inflammation & Immunology, Pfizer Global Product Development. “We are continuing to work closely with the FDA on the development process with the goal of bringing this potential new treatment to patients living with alopecia areata as soon as possible.”

Breakthrough Therapy designation was initiated as part of the Food and Drug Administration Safety and Innovation Act (FDASIA) signed in 2012. As defined by the FDA, a Breakthrough Therapy is a drug intended to be used alone or in combination with one or more other drugs to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. If a drug is designated as a Breakthrough Therapy, the FDA will expedite the development and review of such drug.

Pfizer is also working with the European Medicines Agency (EMA) on the clinical development program for PF-06651600.