BioSpectrum
the business of Bio & Health Sciences

Upadacitinib availed Breakthrough Therapy Designation from USFDA

12 January 2018 | News

U.S. Food and Drug Administration granted Breakthrough Therapy Designation to AbbVie's Upadacitinib for Atopic Dermatitis

AbbVie is a global, research and development-based biopharmaceutical company.

The company announced the U.S. FDA has granted Breakthrough Therapy Designation for the new, once-daily oral JAK1-selective inhibitor upadacitinib (ABT-494) in adult patients with moderate to severe atopic dermatitis.

This Breakthrough Therapy Designation is supported by positive Phase 2b results previously announced in September 2017 and marks 13 Breakthrough Therapy Designations granted to AbbVie's investigational treatments since the company's inception in 2013.

Upadacitinib is not approved by regulatory authorities and its safety and efficacy have not been established.

Atopic dermatitis, a chronic inflammatory skin disease, is characterized by skin erosion, oozing and crusting, redness, intense itching (pruritus) and dry skin.

Symptoms can appear as a rash on the skin, or the skin may become thickened and leathery.

The FDA's Breakthrough Therapy Designation program is intended to expedite the development and review of medicines.

AbbVie will present additional data from the Phase 2b trial at upcoming scientific congresses.