

PRESS RELEASE

For medical, trade and consumer media

AbbVie's HUMIRA® (Adalimumab) Approved by European Commission to Treat Adolescents with Hidradenitis Suppurativa (HS)

- *Decision marks first and only treatment option for patients aged 12 and older with active moderate to severe hidradenitis suppurativa, a painful, chronic inflammatory skin disease*
- *Hidradenitis suppurativa is estimated to affect 1 – 4 percent of the world's population¹⁻²*

MAIDENHEAD, UK, 16 December, 2016 — AbbVie, a global biopharmaceutical company, today announced that the European Commission has approved HUMIRA® (adalimumab) for the treatment of active moderate to severe hidradenitis suppurativa (HS) in adolescents from 12 years of age with an inadequate response to conventional systemic HS therapy. Adalimumab is now the first and only biological treatment option for HS patients 12 years of age and older in the European Union.

“Adolescent HS patients can experience painful and embarrassing symptoms that can have a considerable impact on their daily lives and emotional state,” said Professor Christos Zouboulis, Director, Departments of Dermatology, Venereology, Allergology and Immunology, Dessau Medical Center, Dessau, Germany. “Painful HS lesions can limit activity, school attendance and exercise, potentially having a profound impact on adolescent patients.”

Hidradenitis suppurativa, sometimes referred to as "acne inversa" by dermatologists, is a painful, debilitating, chronic inflammatory skin disease estimated to affect 1 – 4 percent of the world's population.¹⁻² The condition is characterised by inflamed, painful lesions typically located around the armpits and groin, on the buttocks and under the breasts.¹⁻² HS can have considerable impact on patients' quality of life, physical activities and emotional state.¹⁻³ The disease can be challenging to diagnose, with studies showing it can take up to eight years for people with HS to receive an accurate diagnosis.^{1-2,4}

“This approval is a significant milestone for this young population who, up until this point, had no approved treatments available to them,” said Alice Butler, UK Medical Director, AbbVie. “This label expansion for adalimumab further demonstrates AbbVie's commitment to providing new solutions for patients living with serious dermatologic diseases.”

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Notes to Editors

About Adalimumab and Adolescent HS

Efficacy of HUMIRA for the treatment of adolescent patients with HS is predicted based on the demonstrated efficacy and exposure-response relationship in adult HS patients and the likelihood that the disease course, pathophysiology, and drug effects are substantially similar to that of adults at the same exposure levels. Safety of the recommended adalimumab dose in the adolescent HS population is based on cross-indication safety profile of adalimumab in both adults and paediatric patients at similar or more frequent doses.

Full summary of product characteristics is available at www.medicines.org.uk/emc.

Globally, prescribing information varies; refer to the individual country product label for complete information.

About AbbVie

AbbVie is a global, research-based biopharmaceutical company formed in 2013 following separation from Abbott Laboratories. The company's mission is to use its expertise, dedicated people and unique approach to innovation to develop and market advanced therapies that address some of the world's most complex and serious diseases. Together with its wholly-owned subsidiary, Pharcyclics, AbbVie employs more than 28,000 people worldwide and markets medicines in more than 170 countries. For further information on the company and its people, portfolio and commitments, please visit www.abbvie.co.uk.

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