



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Press Office

Press release

First medicine recommended for approval for hidradenitis suppurativa

Treatment of this serious skin condition to be added to Humira's approved uses

The European Medicines Agency (EMA) has recommended extending the use of Humira (adalimumab) to include treatment of adults with active moderate to severe hidradenitis suppurativa (acne inversa), who have failed to respond to conventional systemic treatments. Hidradenitis supportiva is a chronic skin disease that causes abscesses and scarring on the skin – usually around the groin, buttocks, breasts and armpits. Humira is the first medicine that is recommended for approval for the treatment of this disease in the European Union (EU).

Humira was first authorised in the EU in September 2003 for the treatment of active rheumatoid arthritis. The use of Humira was later extended to include the treatment of other inflammatory autoimmune conditions in adults and children, including juvenile idiopathic arthritis, psoriatic arthritis, ankylosing spondylitis, plaque psoriasis, Crohn's disease and ulcerative colitis.

The active substance in Humira, adalimumab, is a monoclonal antibody. It has been designed to attach to tumour necrosis factor-alpha (TNF), which is involved in causing inflammation and is found at high levels in patients with the types of autoimmune diseases that Humira is used to treat. By blocking TNF-alpha, adalimumab reduces the inflammation and other symptoms of the diseases.

Hidradenitis suppurativa is estimated to affect about 1% of the population in any one year, and is 2 to 5 times more common in women than men. It ranges from mild to severe forms, but it can be progressive in some people. It is characterised by recurrent inflamed nodules and abscesses, which may form fistulas, leak pus and cause scarring. Hidradenitis suppurativa can have a considerable impact on patients' daily lives, their work/school attendance, physical activities, and emotional state.

Currently, there are no approved medicines for the treatment of hidradenitis suppurativa in the EU, but there are treatment recommendations from learned societies including antibiotics to treat infections. Surgery and/or laser treatments are sometimes used in severe cases. The EMA's Committee for Medicinal Products for Human Use (CHMP) considered that there is an unmet medical need for treatment of this condition when conventional treatments have failed.



The recommendation from the CHMP is based on the results of two main studies in 633 people with moderate to severe hidradenitis suppurativa. Patients in these studies were randomly assigned to receive either Humira or placebo in addition to daily use of a topical antiseptic. Both studies showed that patients given Humira had greater reductions in the numbers of abscesses and inflammatory nodules than patients given placebo.

The adverse events reported during the clinical trials of Humira for hidradenitis suppurativa were generally similar to those seen with Humira used in its other indications. There are some known risks with Humira including risks of infection and malignancy. A follow-up plan to monitor the long-term safety of Humira was agreed by the CHMP.

The company received scientific advice from the CHMP on clinical aspects of the application. This is one of the Agency's main tools to facilitate and stimulate research and development within the EU.

The opinion adopted by the CHMP at its June 2015 meeting is an intermediary step on Humira's access to adult patients with active moderate to severe hidradenitis suppurativa. The CHMP opinion will now be sent to the European Commission for the adoption of a decision to change the marketing authorisation. Once the extension of indication has been granted, each Member State will take a decision on price and reimbursement based on the potential role/use of this medicine in the context of its national health system.

Notes

1. This press release, together with all related documents, is available on the Agency's website.
2. The applicant for Humira is AbbVie Ltd.
3. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu.

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