

PRESS RELEASE

For UK Consumer, Medical and Trade Media

AbbVie's HUMIRA® (adalimumab) Now Approved by the European Commission to Treat Certain Forms of Non-Infectious Uveitis, A Disease That Can Severely Impact Vision

MAIDENHEAD, UK, July 5th, 2016 – Humira® (adalimumab) has today received approval from the European Medicines Agency (EMA) as the first and only biologic medicine authorised for patients with certain types of non-infectious uveitis, an inflammatory, painful eye condition¹ that can lead to blindness. Adalimumab is now authorised in the EU, as a treatment option for uveitis affecting the middle, back or multiple parts of the eye, called the uvea, and can be used in adults for whom typical treatment with corticosteroids is insufficient in controlling the inflammation, or where that treatment has started to cause complications¹.

Uveitis is a group of inflammatory eye conditions which can be caused either by infection or abnormal activation of the immune system in the uvea, the middle part of the eye^{2,3}. Non-infectious uveitis can lead to reduced vision or vision loss and is the third-leading cause of preventable blindness worldwide^{4,5,6,7,8}. Although the disease can affect children, it typically occurs in people of working age.

Dr Dolores M Conroy, Director of Research, Fight for Sight, said, "Uveitis is a devastating and under-recognised condition. People can experience painful flares, deteriorating vision and the fear that they may ultimately go blind. It impacts their life at home and work, as undertaking daily tasks such as reading and driving become increasingly difficult. For some, current forms of treatment are not appropriate or do not offer relief. The development of new treatments for uveitis was identified as a top priority by the Sight Loss and Vision Priority Setting Partnership-a consultation with patients and eye health professionals."

Professor Andrew Dick, Theme Lead for Inflammation and Immunotherapy, NIHR Biomedical Research Centre at Moorfields Eye Hospital and UCL Institute of Ophthalmology, said, "Uveitis can be difficult to diagnose and treat, and there are no global guidelines for its treatment. Corticosteroids tend to be the main treatments used, after an infection is ruled out. However these steroids are not appropriate for all patients, have very significant systemic side effects and may cause glaucoma and cataracts."

He continued, "This new licence for adalimumab is excellent news for patients, presenting the first approved biologic medicine for certain types of uveitis. Due to the long-term impact and risk of complications, it is critical that uveitis is treated appropriately and that inflammation is fully controlled. For many, this option could halt the decline in their vision, preventing loss of vision, and giving immeasurable benefits in terms of their lifestyle and independence."

People with uveitis experience recurrent 'flares' or episodes of the disease, during which symptoms can include red, painful eyes and impaired vision³. Recurrent flares and complications associated with the

condition, such as glaucoma or cataracts, not only affect a patient's vision and ability to undertake daily tasks, but can also cause irreversible deterioration, which over time, can cause blindness^{3,4}. Adalimumab has been shown to decrease the risk of flares and prolong visual clarity⁹.

Treatment of uveitis varies depending on the location and severity of the inflammation and the underlying cause. Until now treatment has been limited to corticosteroids, supplemented if necessary by immunosuppressants. However, treatment with corticosteroids can be associated with a number of complications, and some patients may require a steroid-sparing therapy, and therefore need a different form of treatment to control the inflammation in the eye^{3, 10}.

The approval of adalimumab now provides clinicians with a biologic alternative, addressing the unmet need for swift escalation.

The licence was based on data from VISUAL-I and VISUAL-II clinical trials, which demonstrated that patients with active and controlled non-infectious intermediate, posterior and panuveitis treated with HUMIRA had a significantly lower risk for uveitic flare or decrease in visual acuity, compared to placebo.

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Notes to editors

About the European Marketing Authorisation

More information about the marketing authorization can be found here: (insert link)

About VISUAL-I and VISUAL-II

The pivotal clinical trials investigated active and inactive non-infectious, intermediate, posterior and panuveitis. Both trials were double-masked, randomized and placebo-controlled. VISUAL-I and VISUAL-II clinical trials were randomised 1:1 and patients treated with HUMIRA received an 80 mg baseline loading dose followed by 40 mg given by subcutaneous injection every other week for up to 80 weeks. The primary endpoint in the VISUAL-I and VISUAL-II studies was time to treatment failure (TF). To be considered a TF, any 1 of these 4 criteria needed to be present in at least one eye: new lesions, anterior chamber (AC) cell grade, vitreous haze and visual acuity.^{11,12}

The VISUAL-I study found that compared to placebo, patients on HUMIRA were less likely to experience TF (hazard ratio=0.5; 95 percent CI, 0.36–0.70; P<0.001). Median time to TF was prolonged by 87 percent, from 13 weeks for placebo (PBO) to 24 weeks for HUMIRA.¹¹ In the VISUAL-II study, the median time to TF was 8.3 months for placebo (PBO) and not estimable for adalimumab (ADA), as more than half of the ADA-treated patients did not experience TF (hazard ratio=0.57; 95% CI, 0.39-0.84; P=0.004). No significant differences were observed between serious adverse events (SAEs), serious infections and the overall rate of adverse events (AEs) between HUMIRA and placebo.¹²

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, Pharmacyclics, 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

About Humira (adalimumab):

For further information, please see the Summary of Product Characteristics:

<http://www.medicines.org.uk/emc>

About the NIHR:

The National Institute for Health Research (NIHR) is funded by the Department of Health to improve the health and wealth of the nation through research. Since its establishment in April 2006, the NIHR has transformed research in the NHS. It has increased the volume of applied health research for the benefit of patients and the public, driven faster translation of basic science discoveries into tangible benefits for patients and the economy, and developed and supported the people who conduct and contribute to applied health research. The NIHR plays a key role in the Government's strategy for economic growth, attracting investment by the life-sciences industries through its world-class infrastructure for health research. Together, the NIHR people, programmes, centres of excellence, and systems represent the most integrated health research system in the world. For further information, visit the NIHR website www.nihr.ac.uk

NIHR Biomedical Research Centre at Moorfields Eye Hospital NHS Foundation Trust and UCL Institute of Ophthalmology was established in April 2007 and awarded a second five-year term by the NIHR from April 2012. Its purpose is to conduct 'translational research' that is designed to take advances in basic medical research from the laboratory to the clinic, enabling patients to benefit more quickly from new scientific breakthroughs. Our centre is currently one of 11 biomedical research centres that were awarded in 2012 to NHS/university partnerships with an outstanding international reputation for medical research and expertise, and experience of translating that research into the clinical setting. For further information, please visit www.brcophthalmology.org.

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