



## PRESS RELEASE

For UK consumer, medical and trade media

### AbbVie's HUMIRA® (adalimumab) Approved by European Commission<sup>1</sup> to Treat Paediatric Patients with Chronic Non-infectious Anterior Uveitis

- *Decision marks AbbVie's HUMIRA® (adalimumab) as the only approved biologic treatment option in the European Union for paediatric patients from 2 years of age with chronic non-infectious anterior uveitis who have had inadequate response to conventional therapy<sup>1</sup>*
- *The approval is based on results from SYCAMORE<sup>2</sup>, an investigator-initiated clinical trial, which showed that adalimumab combined with methotrexate significantly delayed the time to treatment failure compared to methotrexate plus placebo in children with active JIA-associated uveitis<sup>2</sup>*

**MAIDENHEAD, UK, 11 September 2017** — AbbVie, a global biopharmaceutical company, today announced that the European Commission (EC) has approved HUMIRA® (adalimumab) for the treatment of chronic non-infectious anterior uveitis in paediatric patients from two years of age who have had an inadequate response to or are intolerant to conventional therapy, or in whom conventional therapy is inappropriate.<sup>1</sup> Adalimumab is now the only approved biologic treatment option for chronic non-infectious anterior uveitis in children aged two years and older in the European Union.

“This approval marks an important milestone for paediatric uveitis patients who, up until this point, had no licensed biologic treatment options available to them,” said Alice Butler, UK Medical Director, AbbVie Ltd. “This label expansion for adalimumab is a further step in AbbVie’s dedication to addressing the unmet needs for both adult and paediatric patients living with serious immune-mediated inflammatory diseases.”

Uveitis is an inflammation of the uvea, which includes the iris, choroid and the ciliary body in the eye.<sup>3</sup> If left untreated, it can lead to vision loss, including cataracts, glaucoma and cystoid macular oedema (CME).<sup>4,5</sup> Severe vision loss has been estimated to occur in 25 to 30 percent of paediatric uveitis cases, making early diagnosis and treatment essential to preserve vision in children with the disease.<sup>4,6</sup> JIA is the most common systemic disorder associated with uveitis in children accounting for more than 75 percent of cases of paediatric anterior uveitis.<sup>7</sup>

“Paediatric uveitis is a debilitating and potentially blinding condition, and the challenges both paediatric patients and their carers face can be overwhelming,” said Professor Athimalaipet Ramanan, paediatric rheumatologist at University Hospitals Bristol NHS Trust and principal investigator of the SYCAMORE study. “The SYCAMORE study showed that adalimumab in combination with methotrexate significantly delayed the time to treatment failure compared with methotrexate plus placebo. These results demonstrate adalimumab has the potential to help many children who have failed standard treatments

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AbbVie Ltd  
AbbVie House  
Vanwall Business Park  
Vanwall Road  
Maidenhead, Berkshire SL6 4UB

OFFICE +44 (0)1628 561090  
[www.abbvie.co.uk](http://www.abbvie.co.uk)

Registered Number: 08004972  
Registered Office: AbbVie House, Vanwall Business Park,  
Vanwall Road, Maidenhead, Berkshire SL6 4UB



preserve their eyesight from the ocular complications associated with chronic non-infectious anterior uveitis.”

The SYCAMORE clinical trial is a randomised controlled study of the clinical efficacy and safety of adalimumab combined with methotrexate versus methotrexate plus placebo for the treatment of active JIA-associated uveitis. It was sponsored by the University Hospitals Bristol NHS Foundation Trust and coordinated by the Clinical Trials Research Centre at the University of Liverpool. The Independent Data Safety and Monitoring Committee (IDSMC) recommended unmasking the trial early after 90 randomised patients with active JIA-associated uveitis showed that adalimumab combined with methotrexate controlled ocular inflammation better and was associated with a significantly lower rate of treatment failure, defined according to several criteria, including multiple components of intraocular inflammation than placebo.<sup>2</sup>

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## Notes to editors

### About the SYCAMORE Trial<sup>2</sup>

The SYCAMORE clinical trial was sponsored by the University Hospitals Bristol NHS Foundation Trust and coordinated by the Clinical Trials Research Centre at the University of Liverpool. The study was supported by grants from the National Institute for Health Research Health Technology Assessment Programme and Arthritis Research UK. In this multicentre, double-masked, randomised, placebo-controlled trial, researchers assessed the efficacy and safety of adalimumab in children and adolescents two years of age and older who had active JIA-associated uveitis. Patients who were taking a stable dose of methotrexate were randomly assigned in a 2:1 ratio to receive either adalimumab (at a dose of 20 mg or 40 mg, according to body weight) or placebo, administered subcutaneously every two weeks. Patients continued the trial regimen until treatment failure or until 18 months had elapsed. Including a 6 months off-study drug period, they were followed for up to two years after randomisation. The primary endpoint was the time to treatment failure, defined as meeting at least one of the following criteria: multiple components of intraocular inflammation, worsening or development of ocular comorbidities, use of concomitant medications that were not allowed or that did not follow pre-specified criteria, and suspension of treatment for an extended period of time.

The Independent Data Safety and Monitoring Committee (IDSMC) recommended unmasking the trial early after 90 randomised patients with active JIA-associated uveitis showed that the addition of adalimumab to methotrexate significantly delayed the time to treatment failure as compared with placebo. The pre-specified stopping criteria were met after the enrolment of 90 of 114 patients. Researchers observed 16 treatment failures in 60 patients (27 percent) in the adalimumab group versus 18 treatment failures in 30 patients (60 percent) in the placebo group (hazard ratio, 0.25; 95 percent confidence interval [CI], 0.12 to 0.49;  $P < 0.0001$  [the pre-specified stopping boundary]). Adverse events were reported more frequently in patients receiving adalimumab than in those receiving placebo (10.07

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events per patient-year [95 percent CI, 9.26 to 10.89] vs. 6.51 events per patient-year [95 percent CI, 5.26 to 7.77]), as were serious adverse events (0.29 events per patient-year [95 percent CI, 0.15 to 0.43] vs. 0.19 events per patient-year [95 percent CI, 0.00 to 0.40]).

### About adalimumab

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

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

### About AbbVie

AbbVie is a global, research-driven biopharmaceutical company committed to developing innovative advanced therapies for some of the world's most complex and critical conditions. The company's mission is to use its expertise, dedicated people and unique approach to innovation to markedly improve treatments across four primary therapeutic areas: immunology, oncology, virology and neuroscience. In more than 75 countries, AbbVie employees are working every day to advance health solutions for people around the world. For more information about AbbVie, please visit us at [www.abbvie.co.uk](http://www.abbvie.co.uk).

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### UK Media Contacts:

Edward Wright  
Luther Pendragon  
T: 020 7618 9100  
E: [abbviecomms@luther.co.uk](mailto:abbviecomms@luther.co.uk)

Joella Webber  
Senior Brand Communications and Patient Relations  
Manager, AbbVie Ltd  
T: 07825 823 755  
E: [joella.webber@abbvie.com](mailto:joella.webber@abbvie.com)

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