PRESS RELEASE

AbbVie’s HUMIRA® (Adalimumab) Approved by European Commission to Treat Children and Adolescents with Severe Chronic Plaque Psoriasis

- HUMIRA is the only Biologic Approved in Europe for Children and Adolescents from Four Years of Age with Severe Chronic Plaque Psoriasis –

18th April 2015 – AbbVie announced today that the European Commission (EC) has granted marketing authorization for HUMIRA® (adalimumab) for the treatment of severe chronic plaque psoriasis in children and adolescents from four years of age who have had an inadequate response to or are inappropriate candidates for topical therapy and phototherapies. With the EC decision, adalimumab now has approval for use in this indication in all member states of the European Union.

“Having psoriasis in childhood can have devastating effects on a child and the development of their confidence and character which can change their whole life. It is therefore really important to have available effective ways to control their skin disease. Often we can do this with topical treatments. Occasionally we do need to use oral treatments or biological treatments. It is therefore really good that we now have approval to use adalimumab for those who need it in the paediatric population.” said Dr Tess McPherson, Consultant Dermatologist, Churchill Hospital and steering committee member for the British Society of Paediatric Dermatology

The marketing authorization is based on the positive results of a Phase 3 study, which will be presented at an upcoming medical meeting.

"With the approval from the European Commission, HUMIRA is now the only biologic approved in Europe to treat children with this condition starting at four years of age, offering an important new option for physicians treating paediatric plaque psoriasis,” said Michael Severino, M.D., executive vice president, research and development and chief scientific officer, AbbVie.

Helen McAteer, Chief Executive, Psoriasis Association said: “Having psoriasis at any age can have a significant life impact but it can be particularly hard for teenagers and young children who are at a really important point in their development. The approval of adalimumab for use in children and teens with

Date of preparation: April 2015
AXCOR150561
severe psoriasis will make a real difference for patients and their families, for whom psoriasis can involve a huge care workload and can be a cause of anxiety. With this in mind, The Psoriasis Association runs a website to offer advice and support specifically for teens and young adults – www.psoteen.org.uk. It is crucial they are given regular assessment and the right treatment so that psoriasis doesn’t define their lives.”

ENDS

About Paediatric Chronic Plaque Psoriasis
According to estimates from the World Health Organization, paediatric psoriasis occurs in 0.70 percent of the paediatric population,¹ with no significant difference by gender.² The chronic autoimmune disease is characterized by the rapid and excessive accumulation of skin cells, which form thick patches of inflamed, scaly skin.³ Paediatric psoriasis has similar characteristics to adult psoriasis, but in children, the psoriatic lesions are typically smaller, thinner, and less scaly.² Beyond the physical challenges of managing the chronic skin disorder, it is also considered to have significant emotional and psychological effects.⁴

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to AbbVie Ltd on 01628 774 933.

Licensed uses for adalimumab
Adalimumab is a prescription only medicine indicated for (please refer to SmPC for full details⁵):

Rheumatoid arthritis
Adalimumab in combination with methotrexate, is indicated for:
- the treatment of moderate to severe, active rheumatoid arthritis in adult patients when the response to disease-modifying anti-rheumatic drugs including methotrexate has been inadequate.
- the treatment of severe, active and progressive rheumatoid arthritis in adults not previously treated with methotrexate.

Adalimumab can be given as monotherapy in case of intolerance to methotrexate or when continued treatment with methotrexate is inappropriate.
Adalimumab has been shown to reduce the rate of progression of joint damage as measured by X-ray and to improve physical function, when given in combination with methotrexate.
Juvenile idiopathic arthritis

Polyarticular juvenile idiopathic arthritis
Adalimumab in combination with methotrexate is indicated for the treatment of active polyarticular juvenile idiopathic arthritis, in patients from the age of 2 years who have had an inadequate response to one or more disease-modifying anti-rheumatic drugs (DMARDs). Adalimumab can be given as monotherapy in case of intolerance to methotrexate or when continued treatment with methotrexate is inappropriate (for the efficacy in monotherapy see section 5.1). Adalimumab has not been studied in patients aged less than 2 years.

Enthesitis-related arthritis
Adalimumab is indicated for the treatment of active enthesitis-related arthritis in patients, 6 years of age and older, who have had an inadequate response to, or who are intolerant of, conventional therapy.

Axial spondyloarthritis

Ankylosing spondylitis (AS)
Adalimumab is indicated for the treatment of adults with severe active ankylosing spondylitis who have had an inadequate response to conventional therapy.

Axial spondyloarthritis without radiographic evidence of AS
Adalimumab is indicated for the treatment of adults with severe axial spondyloarthritis without radiographic evidence of AS but with objective signs of inflammation by elevated CRP and / or MRI, who have had an inadequate response to, or are intolerant to nonsteroidal anti-inflammatory drugs.

Psoriatic arthritis
Adalimumab is indicated for the treatment of active and progressive psoriatic arthritis in adults when the response to previous disease-modifying anti-rheumatic drug therapy has been inadequate. Adalimumab has been shown to reduce the rate of progression of peripheral joint damage as measured by X-ray in patients with polyarticular symmetrical subtypes of the disease and to improve physical function.

Psoriasis
Adalimumab is indicated for the treatment of moderate to severe chronic plaque psoriasis in adult patients who failed to respond to or who have a contraindication to, or are intolerant to other systemic therapy including cyclosporine, methotrexate or PUVA.
Crohn's disease
Adalimumab is indicated for treatment of moderately to severely active Crohn's disease, in adult patients who have not responded despite a full and adequate course of therapy with a corticosteroid and/or an immunosuppressant; or who are intolerant to or have medical contraindications for such therapies.

Paediatric Crohn's disease
Adalimumab is indicated for the treatment of severe active Crohn's disease in paediatric patients (from 6 years of age) who have had an inadequate response to conventional therapy including primary nutrition therapy, a corticosteroid, and an immunomodulator, or who are intolerant to or have contraindications for such therapies.

Ulcerative colitis
Adalimumab is indicated for treatment of moderately to severely active ulcerative colitis in adult patients who have had an inadequate response to conventional therapy including corticosteroids and 6mercaptopurine (6-MP) or azathioprine (AZA), or who are intolerant to or have medical contraindications for such therapies.

Further information about adalimumab is available at www.medicines.org.uk

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. AbbVie employs approximately 25,000 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.

# # #

UK Media Contacts:
Freeha Rafiq
+44 (0) 1628 644326

References

