

European Commission approval makes Enbrel® first and only biologic treatment approved for severe psoriasis in paediatric patients

For the first time, children and adolescents in Europe with psoriasis are now able to benefit from same efficacy and disease control as adults

Wyeth Europa, Maidenhead, UK – Thursday 8 January 2009: The European Commission today granted marketing authorisation of the use of Enbrel® (etanercept) as the first biologic licensed for treatment in children and adolescents with chronic severe plaque psoriasis. The approval by the Commission allows for the treatment of patients between the ages of eight and 17¹ who are inadequately controlled by, or are intolerant to, other systemic therapies or phototherapies. The approval follows a positive recommendation from the Committee for Medicinal Products for Human Use in November 2008 and is based on the results from the 211 study, the first trial of a biologic treatment in plaque psoriasis patients in this age group. This is the sixth indication for Enbrel which is also approved for use in adult rheumatoid arthritis, juvenile idiopathic arthritis, ankylosing spondylitis, adult psoriatic arthritis and adult psoriasis.

“We are delighted by the news of the European Commission’s approval of the use of Enbrel in this younger population which up until now, were unable to access the same treatment options that adults with psoriasis have had for four years,” said Andreas Krebs, President, Wyeth Europe. “Enbrel has a long established efficacy and safety record, with 16 years of collective clinical experience. This approval makes Enbrel the first and only biologic psoriasis treatment licensed for children aged eight to 17 and solidifies Enbrel’s position as the leading psoriasis treatment.”

More than a skin disease

Across Europe, 5.1 million people are estimated to have psoriasis², a distressing chronic inflammatory disease. Approximately 80 per cent of these patients have plaque psoriasis³, which is characterised by red, scaly patches. But psoriasis is more than just a skin disease and can have a significant impact on patients’ quality of life. A third of psoriasis patients first see signs of the disease in childhood,⁴ when they may experience feelings of embarrassment over the appearance of their skin and anxiety about rejection from peers.⁵

Enbrel is effective in children

Results from the 211 study showed that at 12 weeks, 57% of patients receiving Enbrel achieved 75% improvement in the psoriasis area-and-severity index (PASI 75) compared to 11% of the patients receiving placebo. After 36 weeks, 68% of Enbrel patients achieved PASI 75.⁶ Enbrel was found to be well tolerated.

“The approval of Enbrel for severe childhood psoriasis offers an important new treatment option for the control of psoriasis at an age, where only few other treatment modalities are available.” said Professor Jörg

Prinz from the Department of Dermatology at the Ludwig-Maximilians University in Munich, Germany.

"Enbrel is an innovative drug that works by reducing the chronic inflammation that leads to plaque psoriasis. It allows physicians to target psoriatic inflammation at its roots and if used appropriately, offers these young patients the possibility of clear skin and an improved quality of life when other treatments have failed."

Enbrel was the first biologic treatment in Europe for adults with moderate to severe plaque psoriasis when approved in 2004. Enbrel was also the first approved treatment for polyarticular juvenile arthritis in children and adolescents aged four to 17 years (receiving approval in 1999 both in the US and European Union).¹

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For further information, please contact:

Wyeth:

Gill Markham, Communications –
Europe, Middle East and Africa
Direct Tel: +44 1628 692536
Email: markhagl@wyeth.com

Danielle Halstrom, Communications –
Global
Direct Tel: +1 484 865 2020
Email: halstrd@wyeth.com

OgilvyHealthPR:

Mary Barrington-Ward
Tel: +44 207 108 6066
Email: mary.barrington-ward@ohpr.com

To access further media information relating to this press release, additional information on Enbrel and future media announcements, please register on the media centre at www.wyeth.eu. If you subscribe to receive our emails you will get updates as soon as new content is added to the site. Please note you will be able to unsubscribe at any time and we will not pass your details on to any third party.

NOTES TO EDITORS

The 211 study: Enbrel[®] in children and adolescents⁶

The 48 week study involved 211 patients with moderate-to-severe psoriasis between the ages of four and 17 years. During the first 12 weeks of the trial, patients received once weekly injections of either placebo or 0.8mg of Enbrel per kilogram of body weight. All patients then received Enbrel for 24 consecutive weeks. At week 36, 138 patients were randomised to receive placebo or Enbrel to investigate the effects of stopping and re-starting treatment.

At week 12, almost two-thirds (57%) of patients achieved a 75% improvement in the psoriasis area-and-severity index (PASI 75), compared to 11% of patients receiving placebo. At week 36, after 24 weeks of open-label Enbrel, 68% of patients in the Enbrel-Enbrel group and 65% of patients in the placebo-Enbrel group achieved PASI 75. During the treatment withdrawal period, 42% of patients receiving placebo instead of Enbrel, lost their response to treatment.

There were no serious adverse events or serious infections during the 12-week placebo-controlled period and rates of adverse events were similar for Enbrel and placebo. During open-label treatment, three patients developed four serious adverse events. No deaths, cancers, opportunistic infections, tuberculosis or demyelination events were reported. The most common adverse events observed during the 48-week trial in patients treated with Enbrel were upper respiratory tract infection, headache, and nasopharyngitis.

ABOUT ENBREL

Enbrel is a fully human soluble tumour necrosis factor (TNF) receptor. Enbrel was first approved in 1998 for moderate to severe rheumatoid arthritis and has since been used in nearly 500,000 patients worldwide across indications.

Enbrel in the EU is approved for the following indications:

Rheumatoid arthritis

Enbrel in combination with methotrexate is indicated for the treatment of moderate to severe active rheumatoid arthritis in adults when the response to disease-modifying antirheumatic drugs, including methotrexate (unless contraindicated), has been inadequate.

Enbrel can be given as monotherapy in case of intolerance to methotrexate or when continued treatment with methotrexate is inappropriate.

Enbrel is also indicated in the treatment of severe, active and progressive rheumatoid arthritis in adults not previously treated with methotrexate.

Enbrel, alone or in combination with methotrexate, has been shown to reduce the rate of progression of joint damage as measured by X-ray and to improve physical function.

Polyarticular juvenile idiopathic arthritis

Treatment of active polyarticular juvenile idiopathic arthritis in children and adolescents aged 4 to 17 years who have had an inadequate response to, or who have proved intolerant of, methotrexate. Enbrel has not been studied in children aged less than 4 years.

Psoriatic arthritis

Treatment of active and progressive psoriatic arthritis in adults when the response to previous disease-modifying antirheumatic drug therapy has been inadequate. Enbrel has been shown to improve physical function in patients with psoriatic arthritis, and to reduce the rate of progression of peripheral joint damage as measured by X-ray in patients with polyarticular symmetrical subtypes of the disease.

Ankylosing spondylitis

Treatment of adults with severe active ankylosing spondylitis who have had an inadequate response to conventional therapy.

Plaque psoriasis

Treatment of adults with moderate to severe plaque psoriasis who failed to respond to, or who have a contraindication to, or are intolerant to other systemic therapy including cyclosporine, methotrexate or PUVA.

ABOUT WYETH:

Wyeth is one of the world's largest research-based pharmaceutical and health care products companies. It is a leader in the discovery, development, manufacturing, and marketing of prescription drugs and over-the-counter medications. It is also a global leader in vaccines, biotechnology and animal health care.

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