

## Redefining the management of inflammatory disease

*- Ongoing research strengthens a leading role of Enbrel® in effective management of rheumatoid arthritis, ankylosing spondylitis, psoriasis and psoriatic arthritis, combined with real-life patient benefits -*

**Wyeth Europa, Maidenhead, UK, Thursday 26 March 2009:** The focus of this year's Wyeth Media Academy is to put into context recent advances made in the treatment of inflammatory disease. In particular etanercept (Enbrel®) studies will illustrate how ongoing anti-tumour necrosis factor therapy research has contributed to redefining appropriate treatment options for physicians and patients.

### **Enbrel can halt disease progression in patients with rheumatoid arthritis (RA)**

- Remission can be established clinically, radiographically and functionally and the COMET (**CO**mbination of **M**ethotrexate and **ET**anercept in Active Early Rheumatoid Arthritis) study was the first major RA trial to use clinical remission as a primary endpoint. The COMET trial demonstrated successful remission in over 50 per cent of patients in each of three measurement approaches, confirming that Enbrel can help stop RA progression to achieve disease remission and prevent further joint damage.<sup>1,2</sup>
- The benefit of successful treatment for patients can also be determined through assessment of activities of daily living, for example, evaluation of RA patients who minimise the number of work days lost due to their condition. The COMET trial showed that patients treated with Enbrel experienced up to 60 per cent reduction in fatigue<sup>3</sup> and patients with active early RA treated with Enbrel plus methotrexate were almost three times less likely to stop working vs. those patients taking methotrexate alone<sup>4</sup> and missed half as many workdays.<sup>4</sup>
- The COMET results demonstrate the benefits of treating severe rheumatoid arthritis early and the role of Enbrel in stopping the disease from causing further joint damage, allowing many patients to continue with their day-to-day activities.<sup>1,4</sup>

## **Enbrel studies support ASAS/EULAR guideline recommendations on use of anti-tumour necrosis factor (TNF) therapy in ankylosing spondylitis (AS)<sup>5,6</sup>**

- The recently published ASAS/EULAR guidelines for the management of AS recommend anti-TNF treatment in patients with persistently high disease activity despite conventional treatments and reiterate the lack of evidence to support the obligatory use of disease modifying antirheumatic drugs (DMARDs) in axial disease.<sup>5,6</sup>
- The results of the ASCEND study support this recommendation demonstrating that Enbrel was effective in treating the signs and symptoms of active AS in significantly more patients than those receiving the DMARD sulphasalazine and significant differences were reported as early as two weeks:<sup>7,8</sup>
  - 75.5 per cent Enbrel patients vs. 51.3 per cent sulphasalazine patients achieved the primary endpoint of ASAS 20 (20 per cent improvement by Assessment of AS criteria at 16 weeks)<sup>7</sup>
  - Over twice as many patients treated with Enbrel achieved partial remission<sup>8</sup>
  - Enbrel was more efficacious than sulphasalazine in helping patients to achieve improvement in pain, physical function and spinal mobility.<sup>7,8</sup>

“It is becoming evident that the approach to AS treatment should be specific to the condition and not follow that of RA in relation to the use of DMARDs. The ASCEND study demonstrates that partial remission can be achieved in patients treated with etanercept and that improved diagnosis and appropriate treatment can help achieve real-life benefits for patients with AS”, commented Professor Joachim Kalden, Erlangen-Nuremberg, Germany.

## **Enbrel is the first biologic to receive European approval for paediatric psoriasis**

- Enbrel was recently approved by the European Commission for chronic severe plaque psoriasis in children and adolescents making it the first biologic treatment option for children aged eight to 17. The approval was based on results of the 211 study<sup>9</sup> underlining the favourable effects on skin clearance and safety profile<sup>10</sup> of Enbrel.
- Enbrel was one of the first biologic treatments in Europe for adults with moderate to severe plaque psoriasis when approved in 2004.<sup>10</sup> Ongoing studies support its role in providing effective management of the disease, combined with recently published study results in adults from the CRYSTEL (**C**linical **R**andomized **Y**ear-long **S**Tudy Assessing the Safety and Efficacy of **E**nbre**L** in Psoriasis) study demonstrating the significant positive impact of Enbrel on the quality of life of psoriasis patients.<sup>11,12</sup>

- For approximately 30-40 per cent of psoriasis patients, the progression to psoriatic arthritis is probable.<sup>13</sup> Results from the PRESTA (**P**soriasis **R**andomized **E**tanercept **S**Tudy in Subjects with Psoriatic **A**rthritis) study showed that at 24 weeks, two out of three patients with psoriatic arthritis (70 per cent taking 50mg Enbrel twice-weekly for 12 weeks and then 50mg once-weekly for a further 12 weeks and 62 per cent taking 50mg once-weekly for the entire 24 weeks) showed a 75 per cent improvement in the psoriasis area-and-severity index (PASI 75) and a significant improvement in quality of life was measured in both groups of Enbrel patients.<sup>14,15</sup> PRESTA is the first and largest study of its kind where both dermatologists and rheumatologists have come together to investigate the positive effects of Enbrel in this specific patient population.

“The collective evidence presented today affirms the role of anti-TNF treatments in helping to redefine the management of inflammatory disease and how the appropriate treatment for the individual patient can achieve the necessary improvements in these conditions” said Professor Robert Moots, Professor of Rheumatology, University of Liverpool, United Kingdom. “Recent clinical trials have demonstrated the role of these biologics, such as etanercept, in not only achieving significant clinical improvements but also in providing real-life benefits to patients”.

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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](http://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**

### **ABOUT ENBREL<sup>10</sup>**

ENBREL is a fully human soluble tumour necrosis factor (TNF) receptor antagonist. ENBREL was first approved in 1998 for moderate to rheumatoid arthritis and has since been used in 505,000 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. Enbrel is also licensed in the European Union for treatment of chronic severe plaque psoriasis in children and adolescents from the age of 8 years who are inadequately controlled by, or are intolerant to, other systemic therapies or phototherapies.

## ABOUT WYETH:

Wyeth Pharmaceuticals, a division of Wyeth, has leading products in the areas of women's health care, infectious disease, gastrointestinal health, central nervous system, inflammation, transplantation, hemophilia, oncology, vaccines and nutritional products.

Wyeth is one of the world's largest research-driven pharmaceutical and health care products companies. It is a leader in the discovery, development, manufacturing and marketing of pharmaceuticals, vaccines, biotechnology products, nutritionals and non-prescription medicines that improve the quality of life for people worldwide. The Company's major divisions include Wyeth Pharmaceuticals, Wyeth Consumer Healthcare and Fort Dodge Animal Health.

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