

FOR IMMEDIATE RELEASE TO CONSUMER MEDIA



News

NICE Recommends Abbott's Adalimumab (HUMIRA®) for the Treatment of Chronic Plaque Psoriasis

MAIDENHEAD, UK, 25 June 2008 — The National Institute for Health and Clinical Excellence (NICE) today recommended adalimumab (HUMIRA) as a treatment option for adults with severe chronic plaque psoriasis.¹ Psoriasis is a non-contagious, recurrent autoimmune disease that affects around 1.2 million people in the UK, up to 240,000 of whom suffer from the severe form of the disease.^{2, 3}

Contact:
**UK Communications
Department**
01628 644 582

"The Psoriasis Association welcomes the decision from NICE on adalimumab for people with psoriasis which is a complex and difficult condition," said Gladys Edwards, Chief Executive of the Psoriasis Association. "This is a positive addition to the treatment options available for those people with the most severe forms of psoriasis."

Psoriasis causes the development of raised, and often extensive, lesions of reddened skin tissue, which may crack, and bleed, and can afflict any part of the body (the elbows, knees and the scalp are usual sites).⁴ The disease may occur among people of all ages and can be both physically painful and have a serious impact on a person's quality of life.

"This recommendation from NICE is a significant advance in the management of psoriasis," commented Professor Christopher Griffiths, Consultant Dermatologist, Manchester. "It provides dermatologists with an additional, valuable therapy for severe forms of this common, disabling skin disease."

Patients with psoriasis may find the psychological impact of the disease just as debilitating as the physical symptoms. Some people with psoriasis suffer from social exclusion and discrimination.⁵ Although the cause of psoriasis is unknown, it is believed there is a strong genetic component, which may be triggered by such things as injury, infection, skin trauma, certain drugs, physical and emotional stress, smoking, excessive alcohol or hormone imbalances.²

Further information on the recommendation from NICE can be found in the notes to editors below.

-Ends-

Notes to Editors

About the NICE Guidance

NICE has recommend adalimumab as a treatment option for adults with plaque psoriasis for whom anti-tumour necrosis factor (TNF) treatment is being considered and when the following criteria are both met:¹

- The disease is severe as defined by a total Psoriasis Area Severity Index (PASI) of 10 or more and a Dermatology Life Quality Index (DLQI) of more than 10
- When the psoriasis has not responded to standard systemic therapies including ciclosporin, methotrexate and PUVA (psoralen and long-wave ultraviolet radiation); or the person is intolerant of, or has a contraindication to, these treatments.

Primary Care Trusts have a statutory duty to fund NICE technology appraisals within three months of publication. Further information on the NICE guidance can be found at www.nice.org.uk.

Today's guidance from NICE follows positive advice, on June 9th 2008, published by the Scottish Medicines Consortium (SMC) for adalimumab for the treatment of chronic plaque psoriasis and by NICE, on May 28th 2008, for the treatment of severe active ankylosing spondylitis with adalimumab.

About Psoriasis

Psoriasis is an inflammatory skin disease, which occurs as a result of skin cells being produced too quickly. Although it is a chronic progressive condition, its course may be erratic, with flare-ups and remissions.

The most common form, which affects 80 per cent of psoriasis cases, is chronic plaque psoriasis (psoriasis vulgaris), which is characterized by well-demarcated, often systematically distributed, thickened, red, scaly plaques which can crack and bleed. There is considerable variation in both the size and the number of the plaques, which can range from one or two plaques to more widespread involvement. Although the plaques can affect any part of the skin, they are typically found on the extensor surfaces of the knees and elbows, and on the scalp.²

About Adalimumab (HUMIRA®)⁶

Adalimumab (pronounced ā-da-lim-you-mab) is an anti-TNF (tumour necrosis factor) and was developed by Abbott as a treatment for use in a number of chronic inflammatory diseases not adequately controlled by traditional therapies.

Adalimumab is licensed in the UK for the following five immunological conditions:

Psoriasis⁶

Adalimumab is indicated for the treatment of adults with moderate-to-severe chronic 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 (psoralen combined with exposure to UVA).

Psoriatic Arthritis⁶

Adalimumab is indicated for the treatment of active and progressive psoriatic arthritis (PsA) 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.

Rheumatoid Arthritis⁶

Adalimumab in combination with methotrexate (MTX) is indicated for:

- the treatment of moderate-to-severe, active rheumatoid arthritis (RA) in adult patients when the response to disease-modifying anti-rheumatic drugs including MTX has been inadequate.
- the treatment of severe, active and progressive RA in adults not previously treated with MTX.

Adalimumab has been shown to reduce the rate of joint damage in RA as measured by X-ray and improve physical function, when given in combination with MTX. Adalimumab can be given as monotherapy in case of intolerance to MTX or when continued treatment with MTX is inappropriate.⁶

Ankylosing Spondylitis⁶

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

Crohn's Disease⁶

Adalimumab is indicated for treatment of severe, active Crohn's disease (CD), in 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.

For induction treatment, adalimumab should be given in combination with corticosteroids. Adalimumab can be given as monotherapy in case of intolerance to corticosteroids or when continued treatment with corticosteroids is inappropriate.

Dosing

Adalimumab is administered as a subcutaneous injection either as a pre-filled pen or pre-filled syringe. For psoriasis the recommended dosing is an initial dose of 80mg, followed by 40 mg given every other week starting one week after the initial dose.⁶ For the PsA, RA and AS indications, adalimumab is usually administered as 40mg every other week as a single dose.⁶ For CD the recommended dosing is 80mg at week 0 followed by 40mg at week 2 and 40 mg every other week thereafter.⁶

Adalimumab should not be administered in patients with active TB, opportunistic or other severe infections, moderate to severe heart failure (NYHA III/IV) or known hypersensitivity to (any of the components of) adalimumab.

Before initiation of therapy with adalimumab, all patients must be evaluated for infection, including active and latent TB. Patients must be actively and regularly monitored for infections during and for 5 months after treatment. Patients should also be evaluated for non-melanoma skin cancer prior to and during treatment. Other precautions also exist. Please refer to the "Summary of Product Characteristics for full information on adalimumab".

Serious, including fatal, side effects have been reported including infections/sepsis, opportunistic infections, TB, demyelinating disease, malignancies including lymphoma and skin cancers, reactivation of hepatitis B, cytopenia, worsening heart failure and anaphylaxis.

About Abbott

Abbott is a global, broad-based health care company devoted to the discovery, development, manufacture and marketing of pharmaceuticals and medical products, including nutritionals, devices and diagnostics. The company employs more than 68,000 people and markets its products in more than 130 countries.

References

1. National Institute for Health and Clinical Excellence. Adalimumab for the treatment of adults with psoriasis. Guidance June 2008. <http://www.nice.org.uk>
2. National Institute for Health and Clinical Excellence. Etanercept and efalizumab for the treatment of adults with psoriasis. Technology Appraisal Guidance T103. July 2006. <http://www.nice.org.uk>
3. Smith CH *et al.* British Association of Dermatologists guidelines for use of biological interventions in psoriasis 2005. Available at http://www.bad.org.uk/healthcare/guidelines/Biological_Interventions.pdf. Date accessed August 2007.
4. National Institute for Health and Clinical Excellence. Adalimumab for the treatment of psoriasis: Final Scope. August 2007. <http://www.nice.org.uk>
5. Cloote H. Continuing Professional Development - Psoriasis. *Nursing Standard* 2000; 14(45): 47-52
6. Electronics Medicines Compendium Humira (adalimumab) Summary of Product Characteristics. <http://emc.medicines.org.uk/>