

News release for medical media only

▼ **MabCampath® (alemtuzumab) available for first line treatment of B-cell chronic lymphocytic leukaemia (CLL) for whom fludarabine chemotherapy is not appropriate**

Expert group recommends FISH analysis to help identify appropriate treatments for CLL patients

Newbury, Berkshire, 18th February 2008 – Bayer Schering Pharma (BSP) and Genzyme Corporation, today announced the availability of MabCampath® (alemtuzumab) for the first-line treatment of patients with B-CLL for whom fludarabine combination chemotherapy is not appropriate.¹ MabCampath was previously approved for the treatment of B-CLL in patients who have been previously treated with alkylating agents and have failed fludarabine therapy.

“In the Phase III trial MabCampath® produced the highest response rate in patients with chronic lymphocytic leukaemia for any single agent seen in previous front-line trials,” said Dr Peter Hillmen of the department of clinical haematology and haematological malignancy diagnostic service at Leeds teaching Hospital and principal trial investigator for MabCampath®. “The availability of MabCampath® as a first line treatment is a significant advance for patients with B-CLL and provides a new option for those who are not suitable for treatment with fludarabine combination chemotherapy”.

This news comes as the expert group - International Workshop on Chronic Lymphocytic Leukemia (IWCLL) - pre-publish in peer review journal *Blood*, new Guidelines on the Diagnosis and Treatment of CLL recommending 17p FISH analysis is always carried out in clinical trials.² Additionally, as genetic defects may be acquired during the course of the disease ‘the repetition of FISH analysis seems justified prior to subsequent, second and third line treatment’. The group say it is desirable to do the same in general practice.²

For patients with a particular type of CLL - del(17p) – the prognosis is poorer than with other types as it appears to be more resistant to standard treatments. The fluorescence in-situ hybridization test or FISH test can determine if a person has this type of CLL and can aid treatment decisions.²

Philip Ashman, Business Head Unit of BSP’s Oncology Division in the UK noted: “We believe that treatment with MabCampath® earlier in the course of a patient’s B-CLL management represents an important step forward for these patients and we commend the Committee’s thorough review of the MabCampath® clinical data.”

The first line licence has been granted based on data from an international open-label Phase 3 clinical trial comparing MabCampath® with chlorambucil in previously untreated patients with B-CLL.³ These data were published in the *Journal of Clinical*

Oncology in December 2007.³ The study met its primary endpoint by demonstrating superior progression free survival (PFS) in patients treated with MabCampath® versus chlorambucil, with MabCampath reducing the risk of disease progression or death by 42 percent (p=0.0001). Patients receiving MabCampath® also exhibited higher overall and complete response rates with a manageable safety profile, compared to patients who were treated with chlorambucil. Results from this study also demonstrated that patients treated with MabCampath® achieved extended treatment-free intervals, with a median period of two years before requiring additional therapy.

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Press Contacts:

Bayer Schering Pharma
Tel: +44 (0)1635 56 3198
Email: bsp-communications@bayerhealthcare.com

Cohn & Wolfe
Deborah Corcoran
Tel: +44 (0) 207 331 5438
Email: deborah_corcoran@uk.cohnwolfe.com

About Chronic Lymphocytic Leukaemia

Chronic lymphocytic leukaemia (CLL) is the most common leukaemia in the Western world,⁴ and has an approximate incidence of 3 people per 100,000 in the UK.⁵ It is more common with increasing age, with the incidence rising to more than 20 per 100,000 over 70 years of age.⁶ The disease is most commonly diagnosed among people age 55 or older.⁷ CLL is characterized by the accumulation of functionally immature white blood cells (lymphocytes) in the bone marrow, blood, lymph tissue, and other organs. Two types of lymphocytes are present in the blood, B cells and T cells. The majority of this patient population (95%) suffers from a subtype called B-cell chronic lymphocytic leukaemia, or B-CLL.⁸ Patients with CLL have too many abnormal lymphocytes or B cells. As these abnormal or cancerous B cells have a longer than normal life span, they begin to build up and “crowd out” the normal, healthy blood cells in places like the bone marrow. Bone marrow infiltration leads to a lack of healthy blood cells, thus leading to fatigue, susceptibility to bleedings, a weakening of the immune system exposing the patient to a higher risk of infection and can become fatal. Many people with CLL often don’t experience symptoms at first, the symptoms of CLL include fatigue, bone pain, night sweats, fevers, and decreased appetite and weight loss.⁹

FISH Analysis

For patients with a particular type of CLL - del(17p) – the prognosis is poorer than with other types as it appears to be more resistant to standard treatments. The fluorescence in-situ hybridization test or FISH test can determine if a person has this type of CLL and can aid treatment decisions. The latest Guidelines on the Diagnosis and Treatment of CLL from the International Workshop on Chronic Lymphocytic Leukaemia (IWCLL), recommend FISH testing as desirable in general clinical practice prior to initiating CLL therapy.²

About MabCampath

MabCampath works in an entirely different way than chemotherapy. MabCampath is a monoclonal antibody. Monoclonal antibodies are proteins which specifically

recognise and bind to a unique other protein called an antigen. MabCampath® works by targeting CD52 an antigen found on the surface of the abnormal lymphocytes or B cells. When MabCampath® binds to this antigen, it activates the immune system to destroy these targeted cells, while sparing crucial stem cells. The destroyed abnormal cells are gradually removed from the body by normal biological processes.^{1,10} MabCampath has shown that it may benefit patients identified as del(17p).^{11,12}

Genzyme and Bayer Schering Pharma are developing alemtuzumab in oncology, multiple sclerosis and other indications. Bayer Schering Pharma AG, Germany holds exclusive worldwide marketing and distribution rights to alemtuzumab and participates with Genzyme in the design of clinical protocols and conduct of activities for the development of alemtuzumab. The product was launched in its oncology indication in the U.S. in June 2001, where it is marketed by Bayer HealthCare Pharmaceuticals Inc. as Campath®, and in Europe, where it is named MabCampath®, in August 2001.

About Bayer Schering Pharma

Bayer Schering Pharma is a leading, worldwide speciality pharmaceutical company. Its research and business activities are focussed on the fields of oncology, haematology & cardiology, diagnostic imaging, primary care, specialised therapeutics and women's healthcare. With innovative products and using new ideas, Bayer Schering Pharma aims to make a contribution to medical progress and strives to improve the quality of life of patients - a factor of particular importance in Oncology.

Bayer Schering Pharma's portfolio of oncological products includes treatments for both solid and haematological malignancies. Intensive research is ongoing as Bayer Schering Pharma strives to discover and advance therapeutic solutions for the benefit of all cancer patients.

For more information, please visit www.bayerscheringpharma.co.uk

About Genzyme

One of the world's leading biotechnology companies, Genzyme is dedicated to making a major positive impact on the lives of people with serious diseases. Since 1981, the company has grown from a small start-up to a diversified enterprise with more than 9,500 employees in locations spanning the globe and 2006 revenues of \$3.2 billion. In 2007, Genzyme was chosen to receive the National Medal of Technology, the highest honour awarded by the President of the United States for technological innovation. In 2006 and 2007, Genzyme was selected by FORTUNE as one of the "100 Best Companies to Work for" in the United States.

With many established products and services helping patients in nearly 90 countries, Genzyme is a leader in the effort to develop and apply the most advanced technologies in the life sciences. The company's products and services are focused on rare inherited disorders, kidney disease, orthopaedics, cancer, transplant, and diagnostic testing. Genzyme's commitment to innovation continues today with a substantial development program focused on these fields, as well as immune disease, infectious disease, and other areas of unmet medical need.

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References:

¹ MabCampath SPC

² Michael Hallek, Bruce D. Cheson, Daniel Catovsky, Federico Caligaris-Cappio, Guillaume Dighiero, Hartmut Dohner, Peter Hillmen, Michael J. Keating, Emili Montserrat, Kanti R. Rai and Thomas J. Kipps. Blood. doi:10.1182/blood-2007-06-093906. Prepublished online Jan 23, 2008

³ Hillmen et al. Alemtuzumab Compared With Chlorambucil As First-Line Therapy for Chronic Lymphocytic Leukemia. J Clin Oncol. Vol 25, No 35 (December 10), 2007: pp. 5616-5623.

⁴ Elter T., Hallek M., Engert A. Fludarabine in chronic lymphocytic leukaemia. Expert Opin Pharmacother. 2006 Aug; 7(12): 1641-51

⁵ ESMO guidelines working group, Annals Oncol; 2007 18 (Suppl 2):ii49-ii50

⁶ Rai K.R. Chronic lymphocytic leukaemia in the elderly population. Clin Geriatr Med. 1997 May; 13(2): 245-9

⁷ Leukaemia Research <http://www.lrf.org.uk/en/1/infdispatcll.html> [last accessed 30.11.07]

⁸ Peter A. Cassileth MD, Bruce Furie MD, Michael B. Atkins MD, Robert J. Mayer. Clinical Hematology and Oncology - Presentation, Diagnosis, and Treatment. Churchill Livingstone published 2003, Chapter 72 page 690.

⁹ Cancer Research UK <http://www.cancerhelp.org.uk/help/default.asp?page=17966> [last accessed 30.11.07]

¹⁰ MabCampath PIL

¹¹ Stilgenbauer S, Dohner H. Campath-1H-induced complete remission of chronic lymphocytic leukemia despite p53 gene mutation and resistance to chemotherapy. N Engl J Med. 2002;347:452-453

¹² Lozanski G, Heerema NA, Flinn IW, et al. Alemtuzumab is an effective therapy for chronic lymphocytic leukemia with p53 mutations and deletions. Blood. 2004;103:3278-3281.