

NeuTec Pharma PLC
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NeuTec Pharma commences patient recruitment in breast cancer clinical trial using its lead drug Mycograb(R)

19 September 2005 - Manchester, UK: NeuTec Pharma plc ('NeuTec') today announces that it has recruited its first patient in a clinical study in breast cancer patients. The phase Ib, pharmacokinetic, multi-centre, open label study will evaluate the safety and efficacy of Mycograb(R) administered in combination with Docetaxel in metastatic or recurrent breast cancer patients.

According to the American Cancer Society, breast cancer is the most common cancer among women, except for non-melanoma skin cancers and it is estimated that in 2005 about 211,240 new cases of invasive breast cancer will be diagnosed among women in the United States. Breast cancer is the second leading cause of cancer death in women, exceeded only by lung cancer. The chance that breast cancer will be responsible for a woman's death is about 1 in 33 (3%). In 2005, about 40,110 women and 470 men will die from breast cancer in the United States. Currently there is no curative therapy for metastatic breast cancer despite early diagnosis, and the five year survival rate for advanced cancers is only 18%.

Mycograb(R) is a human genetically recombinant antibody ('grab') that binds to heat shock protein 90 ('hsp90') which has been identified as a tumour marker which appears on the outside of certain cancer cells (as with fungi) and is needed for cancer cell survival. The growth of cancer cells is particularly sensitive to the effects of hsp90's inhibition and this anti-cancer activity has been seen in a series of in vitro studies looking at the killing of human cancer cell lines.

There have been over 460 papers describing the involvement of hsp90 in the development of cancer. Consequently, hsp90 proteins are widely being evaluated as targets for cancer chemotherapy in combination with other drugs and as stand alone therapy. There are 21 on-going trials, involving a variety of cancers, using agents based on variants of the chemical hsp90 inhibitor geldanamycin. Dose-limiting toxicity, however, is a major hurdle in the development of chemical hsp90 inhibitors. Mycograb(R) differs from all other hsp90 inhibitors in having been originally developed for the treatment of fungal infections. It is the subject of an on-going application to

the European Medicines Evaluation Agency ('EMEA') for market authorisation in Europe for the treatment of invasive candidiasis. It has a unique site of action which is not dependent on nucleotide displacement and, being a human antibody-based product, is intrinsically safe.

NeuTec's study is taking place in three centres based in Serbia and Poland and will involve approximately 20 patients who may have received prior cytotoxic treatment as adjuvant therapy and have a measurable lesion. Patients will be administered with six cycles of treatment, three weeks apart. The study's primary objective is to observe the safety and tolerability of Mycograb(R) administered in combination with current gold standard therapy and the secondary objective is to monitor the response rate of the target tumours and overall survival and progression-free survival through 7 months post treatment.

Prof James Burnie said, 'We already have evidence that Mycograb(R) has clinical efficacy in patients with invasive candidiasis. We are now further exploring potential activity of Mycograb(R) in breast cancer as a part of our ongoing programme of exploring the drug's potential in a range of other indications.'

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Notes to editors:

NeuTec Pharma plc is a biopharmaceutical company formed in 1997 specialising in the development of genetically recombinant antibodies, or 'grabs', for the treatment of life-threatening infections. In February 2002 the

Company's equity was admitted on the Alternative Investment Market ('AIM') of the London Stock Exchange.

The development of NeuTec's products differs from the traditional approach used by conventional pharmaceutical companies which screen numerous chemical compounds for activity against bacteria and fungi. Many of these compounds will be too toxic for human use. In contrast, NeuTec identifies naturally occurring potentially protective antibodies from patients who have recovered from infection and then uses its platform technology Fabtec(R) for the identification of new therapeutic antibody fragments. As a result, these 'grabs' are likely to be intrinsically safer than antibiotics.

NeuTec's two leading drug candidates are Mycograb(R), which targets systemic candidiasis, and Aurograb(R), which targets Staphylococcus aureus including methicillin-resistant Staphylococcus aureus ('MRSA'). A confirmatory study completed in 2004 using Mycograb(R) demonstrated that use of this hsp90 inhibitor is highly effective in improving outcome and reducing mortality when given in combination with conventional antifungal drugs to patients with invasive fungal infections.

Hsp90 and cancer: there is increasing evidence that hsp90, as a molecular chaperone, plays an important role in the development, maintenance and progression of cancer, and as such hsp90 has been identified as a target for new cancer therapies (Workman 2004). Normally in humans, hsp90 is resident within the cell and functions intracellularly, acting as a cytosolic molecular chaperone (Picard 2004). But in certain types of cancers it appears on the cell surface. Hsp90 can function in the extra cellular space and has recently been found to be necessary for the extra cellular maturation of the matrix metalloproteinase MMP2, which is a secreted protein, known to be mediator of invasion by cancer cells. By assisting MMP2, hsp90 promotes the migration of cancer cells through the extra cellular protein meshwork (Picard 2004). Antibodies to hsp90 have been shown to cause a loss of invasiveness.