

# **NeuTec Pharma plc**

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## **NeuTec Pharma announces encouraging phase IIb data on its MRSA drug, Aurograb**

13 June 2003 - Manchester, UK: NeuTec Pharma plc ('NeuTec'), the biopharmaceutical company targeting drug-resistant, life-threatening infections, announces encouraging data from a phase IIb study for the treatment of MRSA infection with the company's drug Aurograb(R).

The phase IIb study was designed to look for tolerability and the pharmacokinetic profile of Aurograb(R) and follows the first clinical safety data announced in January which showed that there were no concerns over the toxicological profile of Aurograb(R). The latest study found the drug to be well tolerated and demonstrated a profile that suggests likely activity against MRSA. Aurograb(R) has activity on its own against strains of MRSA, but when combined with vancomycin, the current 'gold standard' treatment, is more effective than either drug used on its own. This efficacy is also evident with strains demonstrating partial resistance to vancomycin.

### **MRSA**

Staphylococcus aureus infection, commonly referred to as MRSA (Methicillin Resistant Staphylococcus aureus), has increased during the last two decades with blood-born infections having a mortality rate of up to 60%. The costs of sepsis, the infection of the blood or other tissues by bacteria, are as high as \$50,000 per patient and are reported to have resulted in an economic burden of nearly \$17 billion per annum in the USA, where it is the 10th leading cause of death.

The dominant hospital-acquired bacteria causing sepsis are the methicillin resistant strains of S.aureus (MRSA) which cause infection resulting in a higher mortality than the methicillin sensitive strains. These infections are typically treated by vancomycin but strains have been reported with partial resistance to vancomycin in Japan, Europe and the USA. In Michigan, USA, a fully-resistant strain of MRSA has been identified. NeuTec has developed a genetically recombinant antibody fragment Aurograb(R) for the treatment of severe MRSA infection.

### **Phase II studies**

In the phase IIa study, announced in January, patients with MRSA infection were given escalating single doses of Aurograb(R) with vancomycin. The resulting safety data allowed NeuTec to progress to the phase IIb study now being reported.

In this trial, nine patients with either systemic or localised infection due to MRSA were given a combination of Aurograb(R) (1mg/kg bd) and vancomycin intravenously for a period of five days.

All patients had complicated skin and soft tissue infections due to MRSA either as a result of trauma, surgery or cancer. In one patient, with a positive blood culture and local wound, infection was clinically cured after four days of combined drug therapy. In six further patients, the infection was localised and MRSA stopped growing after an average of 5.8 days. This included one patient who had been persistently positive for MRSA for a year. Previous studies treating Staphylococcal infection have used courses of 7-28 days of vancomycin with an average length of therapy of 12.6 days for patients with soft tissue infection. In two patients the infection was local and complicated by a surgical implant so that MRSA carriage persisted as expected and its eradication was dependent on implant removal.

The primary end point of the phase IIb trial was to demonstrate that blood levels of Aurograb(R) were sufficient to be therapeutic. This was achieved with an average daily C(max) varying from 11-15.7 ug/ml, which was above the level required to produce a therapeutic response in the laboratory. There were no drug-related, clinically significant adverse events reported.

The data from this trial has encouraged NeuTec to proceed to a double-blind phase II/III (pivotal) trial for Aurograb(R). The trial will compare the effects of Aurograb(R) in combination with vancomycin versus vancomycin alone in the treatment of MRSA infection.

In addition, NeuTec also announces today that it has received a Notice of Allowance prior to patent grant from the US Patent Office covering the target within MRSA against which Aurograb(R) works.

Professor James Burnie, Chief Executive of NeuTec, said, 'We are very encouraged by this early clinical data. MRSA is a life-threatening disease with few treatment options. We are committed to advancing the clinical trials of Aurograb(R) and will provide a further update in due course.'

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Notes to editors:

NeuTec Pharma plc is a biopharmaceutical company formed in 1997 which specialises 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 bacterial and fungal infections and then uses these to generate 'grabs' to treat these infections. 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').

NeuTec uses its platform technology Fabtec(R) for the identification of new therapeutic antibody fragments. This technology is available for licensing.

MRSA is regarded as the hospital 'superbug' by virtue of its ability to spread and cause outbreaks with a high mortality of up to 50%. This is by producing abscesses, pneumonia and blood poisoning. Hospital-acquired infections killed up to 5,000 patients in the UK last year. Strains have been reported from Japan, USA and Europe, which are intermediate or fully resistant to this antibiotic.