

# ***NeuTec Pharma plc***

## **Leading US Journal Publishes Mycograb<sup>®</sup> Trial Results**

### **Editorial Concludes that Mycograb<sup>®</sup> Could Hasten the Arrival of a “Third Age of Antimicrobial Therapy”**

**20<sup>th</sup> April 2006 - Manchester, UK:** *NeuTec Pharma plc* ("*NeuTec*" or the "*Company*"), the biopharmaceutical company targeting drug-resistant, life-threatening infections, announces that a leading US publication for infectious diseases, *Clinical Infectious Diseases* ("CID"), has peer reviewed the results of the Mycograb<sup>®</sup> pivotal trial and concluded that Mycograb<sup>®</sup>, a novel and unique antifungal, could "hasten the arrival of a third age of antimicrobial therapy".

Mycograb<sup>®</sup> is a human recombinant monoclonal antibody against heat shock protein 90 that, in laboratory studies, was found to have synergy with amphotericin B and caspofungin against a broad spectrum of *Candida* species.

The editorial commentary on the paper describing the double-blind, randomized study which was completed in July 2004, referred to the trial results as "remarkable" and "dramatic". The trial was conducted to determine whether Mycograb<sup>®</sup> plus lipid-associated amphotericin B was superior to placebo plus amphotericin B in patients with culture-confirmed invasive candidiasis.

#### **Results:**

Of the 139 patients enrolled from Europe and the US, 117 were included in the modified intention-to-treat population. The results were as follows:

- A complete overall response by day 10 was obtained for 29 (48%) of 61 patients in the amphotericin B group, compared with 47 (84%) of 56 patients in the Mycograb<sup>®</sup> combination therapy group,  $P < 0.001$ .

The following efficacy criteria were also met:

- Clinical response - 52% vs 86%,  $P < 0.001$ ;
- Mycological response – 54% vs 89%,  $P < 0.001$ ;
- *Candida*-attributable mortality 18% vs 4%,  $P < 0.025$ ;
- Over double the rate of culture-confirmed clearance of infection  $P = 0.001$ .

Additionally, Mycograb<sup>®</sup> was found to be well tolerated.

#### **Conclusion:**

The conclusion of the paper is that "Mycograb<sup>®</sup> plus lipid-associated amphotericin B produced significant clinical and culture-confirmed improvement in outcome for patients with invasive candidiasis."

Mycograb<sup>®</sup> is the subject of a Common Technical Document (“CTD”) for market authorisation submitted to the EMEA in March 2005. Progress to date remains consistent with a market launch by the end of 2006.

**Prof. Arturo Casadevall from the Albert Einstein College of Medicine, New York, said:**

“Candidiasis is associated with an unacceptably high mortality rate even when treated with antifungal drugs. Prof. Pacyl’s report shows that the administration of Mycograb<sup>®</sup> in combination with amphotericin B to patients with invasive candidiasis reduced candida-attributable mortality over 4-fold, markedly improved the overall response, and increased the rate of culture-confirmed clearance of *Candida* species, compared with the administration of amphotericin B alone. This could hasten the arrival of the third-age of antimicrobial therapy.”

**Prof. James Burnie, Chief Executive of NeuTec, commented:**

"We are delighted that Mycograb<sup>®</sup> has generated so much interest and that now the results of the pivotal trial have been published in a prestigious journal in the field of infectious diseases. We believe that Mycograb<sup>®</sup> represents a new era in the treatment of life-threatening infections. This drug reduces the mortality of an infection which kills around 1 in 5 patients on standard antifungal therapy. Mycograb is currently being given under a compassionate use programme, in which it has been used in combination with either amphotericin B or caspofungin.”

**Other indications:**

NeuTec recently reported that patient recruitment was completed in a phase Ib study to evaluate the safety and efficacy of Mycograb<sup>®</sup> in combination with Docetaxel in metastatic or recurrent breast cancer patients. We also recently reported that an IND in the US has been obtained for a double-blind, placebo-controlled, multi-centre phase III study using Mycograb<sup>®</sup> in combination with generic amphotericin B and 5-flucytosine against *Cryptococcus neoformans* – a cause of mortality in HIV infected patients. Hospitals in the US, South Africa and South America have agreed to take part in the study which will commence shortly.

**For further details please contact:**

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