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Biota's HRV Drug successfully completes Phase I Clinical Trial

Biota Holdings Limited (ASX:BTA) today announced the successful completion of the second stage of its Phase I human safety and tolerability study of BTA798, a potent inhibitor of human rhinovirus (HRV), the major cause of the common cold. The drug has been shown to be safe and well tolerated at all doses.

Biota intends to advance the development of the drug to Phase II trials to test the efficacy of the drug.

Commenting on the trial results today, Biota Chief Executive Officer, Peter Cook said, *"The successful completion of the Phase I trial is a significant milestone in the development of what could be a world-first antiviral treatment for HRV in high risk patients.*

A safe and effective treatment for HRV would be a major breakthrough for high risk sufferers of asthma, chronic obstructive pulmonary disease, cystic fibrosis, and in patients with compromised immune systems for whom the common cold can trigger events leading to serious illness and hospitalisation".

The trial involved a total of 32 healthy volunteers and studied the effects of two dose levels, once or twice daily. The study was double-blind and used placebo controls. Results of the first stage of the study, Phase Ia, were reported on 2 August 2006.

The Phase I trial (Phase Ia and Ib combined) has established BTA798 to be safe and well tolerated in healthy volunteers at all single and multiple doses.

The clinical trial design and the product's data package were approved by an Independent Ethics Committee (IEC) and the Medical & Healthcare Products Regulatory Agency (MHRA) in the United Kingdom, prior to the start of the trial. The trial was conducted in the UK by a specialist contract research organisation.

About BTA798

BTA798 is the product of original research at Biota. It is an orally available, small molecule drug that targets the capsid protein on the surface of the human rhinovirus to stop the spread of the virus infection. While HRV is the principal cause of the common cold, Biota intends to develop BTA798 initially for treatment and prevention of HRV infection in those patients considered to be at greatest risk of serious complications if they contract HRV.

About Phase I Clinical Trials

Phase I clinical trials are carried out to examine the safety, tolerability, and pharmacokinetics (distribution of the drug in blood and other tissues over time) in human volunteers. Phase Ia studies use a single dose in any one volunteer, although overall, the study uses a number of doses which are progressively increased after demonstrated safety at a lower dose. Phase Ib studies follow a similar approach but restrict the number of dosage levels used but repeat the dose at suitable intervals, in line with the expected therapeutic use.

A Phase I study is typically conducted in healthy volunteers.

Approval to conduct a Phase I trial requires many preliminary studies to be completed including the determination of a safe starting dose, usually very low and increased slowly as safety is assessed at each dose.

About Biota

Biota is a leading antiviral drug development company based in Melbourne, with key expertise in respiratory diseases, particularly influenza. Biota developed the first-in-class neuraminidase inhibitor, zanamivir, subsequently marketed by GlaxoSmithKline (GSK) as Relenza. Relenza is currently being stockpiled by a number of national governments as a defence against a threatened influenza pandemic. Biota receives royalties from sales of Relenza.

Biota research breakthroughs have included a series of candidate drugs aimed at respiratory syncytial virus (RSV) or bronchiolitis, licensed to MedImmune Inc. and novel nucleoside analogues designed to treat hepatitis C virus (HCV) infections, licensed to Boehringer Ingelheim International GbmH. Biota has clinical trials underway with its lead compound for human rhinovirus (HRV) infections in patients with compromised respiration or immune systems. In addition, Biota has key partnerships with Sankyo; for the development of second generation influenza antivirals (called LANI or long acting neuraminidase inhibitors) and with Inverness Medical (Thermo Electron); Biota developed the FLU OIA® influenza diagnostics, marketed in the US.

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**Further information available at www.biota.com.au.*

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