



*For Immediate Release*

## **RSV Drug Starts Phase Ia Clinical Trials**

MELBOURNE and GAITHERSBURG, Md., U.S.A. – **(July 17, 2007)**

Biota Holdings Limited (ASX:BTA) and MedImmune Inc., today announced the start of a Phase Ia clinical trial for their respiratory syncytial virus (RSV) antiviral drug, BTA9881, with the goal of providing a treatment for RSV infected infants and adults. Developed from original research by Biota, the drug was licensed to MedImmune on December 14, 2005.

The trial is an oral, single dose escalating, double-blinded, placebo-controlled study in 72 healthy adult volunteers. The primary objective of the trial is to assess the safety and tolerability of BTA9881, with a secondary objective to determine its pharmacokinetic properties in adults. It is being conducted with acceptance by an Independent Ethics Committee (IEC) for the clinical trial centre and by notification to the Australian Therapeutic Goods Administration. Results of the study are expected by the end of 2007.

*"We are pleased to begin the clinical testing stage of this promising anti-RSV target,"* said Genevieve Losonsky, M.D., Vice President of Clinical Development, Infectious Diseases at MedImmune.

Under the terms of the licensing agreement, MedImmune is to provide Biota with a US\$3 million payment upon the initiation of the trial.

Biota CEO Peter Cook stated, *"We have been working very closely with MedImmune over the last 18 months and are delighted to have progressed BTA9881 to clinical trial stage. Biota now has three products in clinic. We have consistently focused on the delivery of milestones to generate value for our shareholders and to progress our products closer to market."*

BTA9881 is a small molecule fusion inhibitor, designed to specifically inhibit the process by which RSV infects a cell. The drug will be used to stop replication of RSV in an infected patient with the aim of clearing the infection or reducing the clinical impact of the disease.

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## **About respiratory syncytial virus**

Respiratory syncytial virus (RSV) infects people of all ages, but particularly infants, causing similar symptoms to influenza. In the northern hemisphere, the RSV season usually starts in the fall and runs through the spring.

The virus is highly contagious, infecting virtually all infants under the age of two and re-infection is common. For example approximately 50 percent of children will experience two RSV infections by the age of two.

RSV is the most common cause of bronchiolitis and pneumonia in infants and, according to the World Health Organisation (WHO), is the single most important cause of severe lower respiratory infections in infants and young children. The Centers for Disease Control and Prevention (CDC) state that 25 to 40 percent of young children will have signs of bronchiolitis and pneumonia during their first RSV infection and 0.5 to 2 percent will require hospitalisation. In particular, RSV can cause severe or life-threatening illness in infants who are born prematurely or those with chronic lung or heart disease.

RSV can also have serious consequences in the elderly and patients with chronic lung or heart disease or with compromised immune systems.

## **About clinical trials**

There are three phases of clinical trials before a new drug can be marketed. The respective phases are:

### **Phase I**

The new medicine is tested in a small group (20-100) of healthy volunteers, often in a hospital setting, to determine its safety profile, including the safe dose range. Pharmacokinetic studies examine how the drug is absorbed, distributed, metabolised and excreted, as well as the duration of its action. There can be a number of Phase I studies and can take from six months to one year to fully complete.

### **Phase II**

Placebo-controlled trials involve approximately 100 to 500 volunteer patients who have the disease being studied. The goal of this phase is to establish if the new medicine effectively treats the disease. There can be a number of such studies before the full completion of Phase II.

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### **Phase III**

The new medicine is tested in placebo-controlled trials with much larger numbers of volunteer patients to generate statistically significant safety and efficacy data, across a variety of age and ethnic groups and other population variables.

### **About Biota**

Biota is a leading antiviral drug development company based in Melbourne Australia, with key expertise in respiratory diseases, particularly influenza. Biota developed the first-in-class neuraminidase inhibitor, zanamivir, subsequently marketed by GlaxoSmithKline as Relenza.

Biota research breakthroughs have included a series of candidate drugs aimed at treatment of respiratory syncytial virus (RSV) disease, licensed to MedImmune Inc. and novel nucleoside analogues designed to treat hepatitis C virus (HCV) infections, licensed to Boehringer Ingelheim. Biota has clinical trials underway with its lead compound for human rhinovirus (HRV) infection in patients with compromised respiration or immune systems. In addition, Biota has key partnerships with Daiichi-Sankyo for the development of second generation influenza antivirals and with Inverness Medical to market Biota developed FLU OIA influenza diagnostics.

### **About MedImmune**

MedImmune strives to provide better medicines to patients, new medical options for physicians and rewarding careers to employees. Dedicated to advancing science and medicine to help people live better lives, the company is focused on the areas of infectious diseases, cancer and inflammatory diseases. With approximately 3,000 employees worldwide, MedImmune is headquartered in Maryland. For more information visit the company's Web site at [www.medimmune.com](http://www.medimmune.com).

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*\*Further information available at [www.biota.com.au](http://www.biota.com.au).*

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