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Melbourne, Australia — 11 August 2008

Human rhinovirus Phase IIa clinical trial commences

Biota Holdings Limited (ASX:BTA) today announced the commencement of dosing in the first Phase IIa challenge study of BTA798, an orally delivered and potent inhibitor of human rhinovirus (HRV). HRV is the major cause of the common cold and is associated with clinical complications for patients with asthma, cystic fibrosis, chronic obstructive pulmonary disease or a compromised immune function.

The aim of the Phase IIa study is to evaluate BTA798 for the prevention (prophylaxis) of HRV infection in approximately 200 healthy volunteers. Each volunteer will be administered either placebo or one of three dose levels of BTA798 before being exposed to an experimental rhinovirus infection.

The double-blind study will be conducted in a controlled quarantine facility in the UK and will monitor the clinical endpoints of viral count and cold symptom improvement. Drug safety and pharmacokinetics will also be monitored to provide further data on BTA798.

The results of this and subsequent Phase IIa studies will be used to assist in selecting doses for treatment and prevention of HRV infection in later clinical studies.

Dosing is expected to be completed by December/January, subject to adequate enrolment rates with volunteers. The full results are expected by the end of April 2009.

About Phase IIa challenge studies

Challenge studies with antiviral drugs expose volunteers to both an induced infection and the drug under study. Challenge studies may examine the efficacy of the drug to either treat the infection (therapy) or prevent the infection (prophylaxis) and the effectiveness of the drug usually is measured by comparison to a placebo. Therapeutic challenge studies require the infection to be established before drug treatment and prophylactic challenge studies require the commencement of drug treatment before exposure to the induced infection. Volunteers included in challenge studies must be both healthy and potentially susceptible to the induced infection.

Biota's initial trial is a prophylaxis study with volunteers exposed to HRV infection by intranasal inoculation.

About human rhinovirus, including in Asthma & COPD

Rhinoviruses can cause up to 50% of all adult colds, and are the predominant cold virus in children. In otherwise healthy individuals, rhinovirus infections are a minor inconvenience and are self limiting, although 75% of common colds suffered by children under 5 years of age in the US, are medically attended.

However, HRV is a major cause of hospitalisation and respiratory distress in individuals with chronic underlying respiratory conditions, including asthma and COPD sufferers.

It is estimated that rhinovirus is associated with approximately 70% of all asthma exacerbations and more than 50% of the hospitalised cases. Although the actual costs of viral exacerbations in asthma have not been measured, they appear to contribute significantly to the total cost of the disease, as they represent some 80% of exacerbations in children and between 40% and 76% in adults.

Chronic Obstructive Pulmonary Disease (COPD) is the fourth leading cause of death in the US. An estimated 10 million adults were diagnosed with COPD in 2000, while a national health survey suggests that as many as 24 million Americans are affected. In 2000, 119,000 deaths, 726,000 hospitalisations and 1.5 million hospital emergency department visits were caused by COPD in the US. Studies suggest that respiratory viruses are associated with more than 35% of acute exacerbations of COPD requiring hospitalisation.

About Biota

Biota is a leading anti-infective 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 a key partnership with Daiichi-Sankyo for the development of second generation influenza antivirals. Inverness Medical markets Biota's co-developed OIA FLU influenza diagnostics.

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

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