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Melbourne, Australia — 26 July 2010

HRV Phase II trial underway in patients

Biota Holdings Limited (ASX:BTA) today announced the commencement of a Phase II clinical trial of the antiviral drug BTA798 in patients with chronic asthma. BTA798 is orally administered and active against human rhinovirus, a virus often associated with the common cold.

The US Food and Drug Administration (FDA) recently provided regulatory clearance for Biota to conduct the study in the US. BTA798 has previously been shown to reduce the incidence of HRV infection in healthy volunteers in a Phase IIa viral challenge study completed in June 2009.

The trial announced today is designed to investigate the impact of BTA798 on cold and asthma symptoms when given shortly after the onset of an infection. Asthmatics often suffer a worsening of their asthma when they develop a cold, so are an important group of patients in whom BTA798 may offer considerable benefit.

The study is a randomised, placebo-controlled, double-blind trial that will involve approximately 60 sites across the United States and may enrol up to 400 patients. It has been timed to coincide with the peak of the northern hemisphere human rhinovirus cold season, which typically commences in late August. With favourable recruitment conditions, the results of the study may be available as early as mid-2011.

Data will be collected on both the efficacy and safety of BTA798. The primary efficacy endpoint is an assessment of the severity and duration of cold symptoms and their impact on patient functioning. Secondary endpoints include incidence and severity of asthma symptoms, changes in lung function, and duration and intensity of viral shedding from the upper respiratory tract.

The trial has been budgeted to cost up to \$25 million over two years.

A number of major pharmaceutical companies have contributed to the study design. Potential partnering discussions have confirmed the need for a product with the profile of BTA798 in asthmatics.

Biota's investment in the current study, with a successful outcome, should significantly enhance the value of any future licence.

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 include a series of candidate drugs aimed at treatment of respiratory syncytial virus (RSV) disease and Hepatitis C (HCV) virus infections. Biota has a clinical trial underway with its lead compound for human rhinovirus (HRV) infection in patients with the underlying respiratory disease of asthma.

In addition, Biota and Daiichi Sankyo co-own a range of second generation influenza antivirals, of which the lead product laninamivir, is in late stage clinical development.

Relenza™ is a registered trademark of the GlaxoSmithKline group of companies.

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

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