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RSV program returned to Biota

Biota Holdings Limited (ASX:BTA) and AstraZeneca UK Limited (AstraZeneca) today announced the completion of its Phase Ia clinical trial for Biota's respiratory syncytial virus (RSV) anti-viral drug, BTA9881 and that further development of this compound has been halted.

BTA9881, the first representative of a novel class of fusion inhibitors developed by Biota, to enter clinical trials, exhibited approximately 100% oral bioavailability in humans and a safety profile in humans comparable to placebo at the doses examined. The pharmacokinetic profile indicated a very long plasma half life in humans. However, the BTA9881 drug profile overall did not meet the desired safety margin required to continue development of this compound.

AstraZeneca's primary interest in Biota's RSV program was the clinical candidate BTA9881. As development of BTA9881 has halted, AstraZeneca has provided notice to Biota that it will terminate the License and Collaboration Agreement as soon as practical. All rights in the Biota RSV program revert to Biota.

Biota intends to invest approximately $3 million in F2010 for the development of promising back-up compounds and to re-licence the program in the future.

About RSV

RSV is the most common respiratory infection in infancy or childhood. Approximately one half of all infants are infected with RSV within the first year of life. Nearly all children have been infected at least once by the time they reach their second birthday. Children born prematurely as well as those with chronic lung disease or congenital heart disease are at the highest risk of severe disease and hospitalisation due to RSV. The virus may also cause severe illness in the other high risk groups such as the elderly, those with underlying respiratory or cardiac disease, and those with compromised immune systems (e.g. HIV patients or patients undergoing chemotherapy).

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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 novel nucleoside analogues designed to treat hepatitis C virus (HCV) infections, licensed to Boehringer Ingelheim, and a series of candidate drugs aimed at treatment of respiratory syncytial virus (RSV) disease. 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 anti-virals.

Relenza™ is a registered trademark of the GlaxoSmithKline group of companies.
**Further information available at www.biota.com.au*

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