biota

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For Immediate Release

Melbourne, Australia — 20 January 2011

IV zanamivir – Phase III study commences

Biota Holdings Limited (ASX:BTA) advises that it has received notification from GlaxoSmithKline (GSK) that it has commenced a pivotal Phase III study of hospitalised patients with influenza, which compares intravenous (IV) zanamivir to oral oseltamivir and the first patient has received treatment.

The primary end point of the study is the time to clinical response in patients with confirmed influenza.

Further details are included in the GSK release, a copy of which is attached.

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 clinical trials underway with its lead compound for human rhinovirus (HRV) infection in patients with compromised respiration or immune systems.

In addition, Biota and Daiichi Sankyo co-own a range of second generation influenza anti-virals, of which the lead product Inavir®, is approved for marketing in Japan.

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

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PRESS RELEASE

Issued: Wednesday 19 January 2011, London UK

GlaxoSmithKline commences Phase III study of intravenous zanamivir for hospitalised patients with influenza

GlaxoSmithKline (GSK) announced today that the first patient has received treatment in a pivotal Phase III study of hospitalised patients with influenza which compares intravenous (IV) zanamivir to oral oseltamivir. The primary endpoint of this study is time to clinical response in patients with confirmed influenza.

The trial has a target enrolment of 462 patients planned in over 20 countries that take into account flu seasons in the northern and southern hemispheres. The study will take approximately three years.

Notes to editors

IV zanamivir is not approved for sale in any country. Zanamivir has been available in countries worldwide in an inhaled form since 1999 and is licensed exclusively and globally from Biota.

GlaxoSmithKline – one of the world's leading research-based pharmaceutical and healthcare companies – is committed to improving the quality of human life by enabling people to do more, feel better and live longer. For further information please visit www.gsk.com

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Cautionary statement regarding forward-looking statements

Under the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995, GSK cautions investors that any forward-looking statements or projections made by GSK, including those made in this announcement, are subject to risks and uncertainties that may cause actual results to differ materially from those projected. Factors that may affect GSK' s operations are described under 'Risk Factors' in the 'Business Review' in the company' s Annual Report on Form 20-F for 2009.

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