

For Immediate Release

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Biota Details GSK's Failures to Support Relenza

After a two year review of more than 200,000 GlaxoSmithKline (GSK) documents, Biota Holdings Limited (ASX:BTA) today filed an Amended Statement of Claim with the Victorian Supreme Court which Biota says provides great detail of its allegation that GSK consistently mismanaged its legal obligation to develop and market the antiviral drug Relenza™ (zanamivir). Relenza is one of only two specific anti-influenza drugs recommended by the World Health Organization for global stockpiling to protect against pandemic influenza, including Avian flu.

Today's amended Statement of Claim updates a writ Biota filed with the Victorian Supreme Court in May 2004, which sought unspecified damages for lost royalties to date as well as future losses through the life of the product's patents. The trial has been set for 1 April 2008.

"In 2004 Biota sued GSK over its failures with Relenza because we were convinced this was the only way to retrieve the value inherent in the product for our shareholders," said Peter Cook, CEO, Biota. *"In the meantime this has been compounded by GSK's failure to properly tackle worldwide concerns over the threat of Avian flu."*

Relenza was first in a new class of antiviral flu drugs, approved for prescription in over 70 countries. It is not known to have the resistance and side effect issues afflicting its chief competitor product Tamiflu® (oseltamivir)ⁱ. Biota's statement says that soon after Relenza's worldwide launch in 2000, GSK withdrew its support for the product, adopting and implementing an "Exit Strategy", with the result that Relenza now holds only a small portion of the estimated US \$2 billion annual global market for antiviral flu drugs, including the stockpiling market to combat the threat of an Avian flu pandemic. Biota is entitled to receive a blended royalty on GSK's sales of Relenza, of approximately 7%.

As a result of GSK's alleged consistent failures in marketing and promoting the product, Biota claims that Relenza has been denied its proper place as a major defence for global populations against the threat of influenza pandemic.

"We now believe that behind GSK's failure to use its best endeavours to develop and market Relenza is systematic failure by GSK in key areas of drug development with disastrous consequences from our point of view as a junior biotechnology company. This is especially disappointing given the trust that companies such as us must place in our senior development partners," said Peter Cook.

In addition, the statement of claim alleges:

- GSK systematically concealed its decisions to withdraw support for Relenza from its junior partner, having adopted an exit strategy and implemented it by successively withdrawing marketing and promotional support for Relenza, while maintaining the contrary position with Biota;
- a number of senior GSK executives including GSK's CEO, Mr J.P. Garnier, were involved in this concealment;
- owing to GSK's dismantling of its manufacturing and distribution system for Relenza and its adoption of a no surplus inventory policy for Relenza, GSK was unable to respond to demands for Relenza from Governments to deal with Avian flu, thereby surrendering the stockpiling market to the competitor product uncontested;
- GSK's belated responses to demands from Governments the world over to come to their aid with supplies of Relenza to manage the threat of Avian flu were tokenistic and lacking in genuine intent to properly market Relenza to this substantial market;
- despite being in possession of trial data to support regulatory approval for prophylaxis as early as 2001, GSK did not pursue prophylaxis (preventative) claims in major markets until very recently. GSK's actions have placed Relenza at a significant competitive disadvantage in relation to the pandemic influenza stockpiling market and have prevented the drug from playing a significant role in combating Avian flu.
- notwithstanding its status as one of the world's largest pharmaceutical companies, GSK's consistent pattern of failures with Relenza cover the full gamut of the drug development process, and include:
 - failures of trial design and execution
 - inappropriate inhaler device selection
 - poor regulatory approval management
 - failures of global marketing and promotion
 - inventory and production too limited to respond to demand
 - failure to exploit existing and new markets

Mr Cook said that Biota strongly contends GSK knew it was in breach of its contract with Biota and that had Biota not taken the decision to litigate against GSK to seek redress, Biota would never have known that GSK had actually taken a clear decision to abandon the drug.

"Biota remains steadfast in its commitment to pursue GSK to redress its failure to do the right thing," Mr Cook said.

About Relenza

Relenza™ is an inhaled drug for treating influenza. It was the world's first in a new class of influenza antivirals known as neuraminidase inhibitors (NAI). Relenza was invented in Australia in 1989 and licensed to the GSK group of companies in 1990. Relenza is effective in the laboratory and in animals against the H5N1 avian influenza virus, the strain of current concern in pandemic planning. Although Relenza is effective via inhalation or intravenous delivery, it is marketed only as an inhaled product. Inhalation delivers high concentrations of the drug directly to the lungs at the site of influenza infection. For treatment of influenza, Relenza is administered via the inhaler, twice daily for five days, or for prophylaxis once daily.

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 respiratory syncytial virus (RSV) or bronchiolitis, 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 (Thermo Electron) to market Biota developed FLU OIA influenza diagnostics.

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

FLU OIA® & FLU OIA A/B® are registered trademarks of Inverness Medical (Thermo Electron Corporation).

ⁱ Tamiflu® is a registered trademark of Roche Laboratories.

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

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