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For Immediate Release

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Important initiatives by GSK to respond to the new influenza A (H1N1) strain

Biota Holdings Limited (ASX:BTA) notes that GlaxoSmithKline (GSK) has announced important initiatives to assist governments and health authorities around the world to respond to the emergence of the new influenza A (H1N1) strain (previously referred to as Swine Flu).

A copy of the full GSK Press Release 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 have included a series of candidate drugs aimed at treatment of respiratory syncytial virus (RSV) disease, licensed to AstraZeneca 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.

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

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

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GlaxoSmithKline update: influenza A (H1N1)

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GlaxoSmithKline (GSK) is committed to supporting governments and health authorities around the world to respond to the emergence of the new influenza A (H1N1) strain.

The company has developed a number of potential interventions which it believes may be of value in efforts to reduce the impact and spread of this new influenza virus. These include the antiviral medicine *Relenza* (zanamivir) and significant vaccine capability and technology, including use of novel adjuvants.

To ensure continuity of supply and manufacture of all its critical medicines and vaccines, GSK has also invoked its own internal pandemic preparedness plan.

Relenza (zanamivir)

GSK has been working with governments to supply *Relenza,* for use in a pandemic situation, since the global spread of avian influenza (H5N1) which began in 2003. *Relenza* has typically been used to diversify and add to government stockpiles of *Tamiflu* (oseltamivir).

Since 2003, *Relenza* has been supplied to 26 governments for the purposes of pandemic stockpiling and on average the product constituted 13% of these stockpiles. Prior to the recent outbreak, the last significant order for *Relenza* was for 10.6 million treatment packs, which was delivered to the UK Government in April 2009.

In relation to the new influenza A (H1N1) strain, the WHO reported that the viruses obtained from the recent human cases were sensitive to oseltamivir and zanamivir but resistant to amantadine and remantadine.[1]

GSK has therefore contacted governments around the world to ascertain demand for *Relenza*, including those countries most affected by the virus, such as Mexico and the USA. As a result, GSK has put in place a series of measures this week to manage existing stocks of *Relenza* and raise production levels:

- GSK has increased production levels for *Relenza* and is now set to produce between 50-60 million treatment packs of *Relenza* per year. The company expects to achieve this rate of output (5 million treatment packs per month) within the next 12 to 14 weeks.

- As of 23rd April 2009, the company had fulfilled all orders received from commercial and public purchasers for *Relenza*. GSK currently has 6 million treatment packs of existing *Relenza* stock. This week, GSK prioritised orders to governments and is working with them to determine the best mechanisms for distribution of *Relenza* either through public or commercial routes.

- The company continues to maintain a close dialogue with governments to build stockpiles of *Relenza*. Going forward, all new orders will be met through an allocation of available stock and phased delivery of stock to be manufactured.

- To further expand production volumes, GSK is in active discussions with several other companies to increase manufacturing capacity of the product. As part of this strategy, GSK is also exploring alternative delivery systems for *Relenza,* beyond the currently approved *Diskhaler* device. GSK plans to discuss these alternatives with regulatory authorities shortly with the objective of agreeing a potentially expedited pathway to approval and availability.

- In China, GSK is working with Simcere Pharmaceuticals as a further option to raise production levels of *Relenza*. GSK granted a voluntary licence to Simcere in 2006 to manufacture and sell products containing zanamivir, in China and a number of other countries, including all 50 of the world's Least Developed Countries (LDCs).

- GSK plans to directly allocate a proportion of newly manufactured stock to LDCs either directly or through multi-lateral agencies. In addition, the company remains committed to engaging in voluntary license discussions with any companies willing to manufacture and supply a zanamivir product for use in developing countries.

Vaccine development

GSK has an active pandemic influenza vaccine R&D programme which includes development of pre-pandemic and pandemic vaccines and use of novel technology such as adjuvants systems.

In 2008, GSK became the first company to obtain a European licence for a pre-pandemic vaccine, *Prepandrix.* This vaccine is designed to raise immune protection against several strains of the H5N1 virus. Also in 2008, GSK received a European licence for *Pandemrix,* a 'mock-up' pandemic vaccine. This approval, which was based on data involving the H5N1 strain, will also enable faster registration of a potential pandemic vaccine against other strains, including H1N1.

This week, GSK has been in continuous discussions with the WHO, the US Centers for Disease Control and Prevention, The US Department of Health and Human Services and the European Centre for Disease Prevention and Control to gain a better understanding of the new influenza A (H1N1) strain. The company is sharing resources and data with these authorities, as requested, to help them develop estimates for manufacturing capability, timing of possible production and use of adjuvant technology in production of a potential pandemic vaccine.

GSK stands ready to begin manufacture of a potential vaccine against the new influenza A (H1N1) strain virus once the WHO and other public health authorities make recommendations for composition of the vaccine.

In the meantime, and in line with recommendations of the WHO and other public health authorities, GSK is continuing to produce and maximise supply of its seasonal influenza vaccine for use in the Southern hemisphere, as it enters the winter season, and for the Northern hemisphere later this year.[2] This remains a critical priority as seasonal flu infects 5% to 15% of the global population and accounts for up to 500,000 deaths each year.[3]

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

Notes to editors

Relenza treatment packs contain a *Diskhaler*, five rotadisks each with four doses of *Relenza*. This is one course of treatment: Two puffs in the morning and two in the evening (so one disk is required per day for five days).

References

1. http://www.who.int/csr/swine_flu/swine_flu_faq.pdf

2. WHO Press Conference 29/04/09

3. WHO factsheet