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Melbourne, Australia — 23 July 2009

GSK Relenza capacity to triple

Biota Holdings Limited (ASX:BTA) notes that GlaxoSmithKline (GSK) has issued a Pandemic (H1N1) Influenza Update on its plans to assist governments and health authorities respond to the emergence of the new influenza A (H1N1) pandemic strain commonly referred to as swine flu.

The plans include a commitment by GSK to increase its annual production capacity of the influenza anti-viral Relenza to 190 million courses by the end of 2009. This increase represents a threefold increase to GSK's previous capacity of 60 million courses.

Production capacity of Relenza in its standard Diskhaler format will be increased from 60 to 90 million courses. Importantly, a further 100 million courses a year of additional capacity will be available as Relenza Rotacaps/Rotahaler. This alternative Relenza treatment has been recently granted temporary approval by Swedish regulators and hence within the EU, for distribution during a pandemic.

The Rotacaps/Rotahaler is widely recognised as a simple, easy to use device. It is already manufactured by GSK for other inhaled products and offers a rapid increase in capacity for Relenza. GSK is in discussion with a number of international regulatory authorities to secure further approvals.

GSK has also indicated that it intends to donate 2 million courses of Relenza to the WHO and on which Biota has agreed to waive royalties.

Biota receives a minimum 7% royalty on global sales of Relenza by GSK and holds patent coverage in the major markets until at least December 2014.

While the positive effect of this expansion on Biota may be significant and GSK have confirmed it has contracts to supply Relenza to over 60 countries, the announcement is focussed on increased manufacturing capacity for Relenza, not orders or sales. GSK has stated that additional regulatory approvals will be required and that the capacity increases are planned for the end of calendar 2009. The expansion of Relenza capacity and any increase in resultant royalty payments, will not effect Biota's cash position until June 2010, at the earliest.

GSK is a significant global supplier of therapeutic products for influenza, including the antiviral Relenza, vaccines, antibiotics and ancillary equipment such as anti-viral face masks, all of which have a recognised beneficial role in the management of the current global influenza pandemic by public health officials.

A copy of the GSK Press Release of 22 July 2009, London, UK, entitled Pandemic (H1N1) 2009 Influenza Update, is attached.

About Relenza

All the way from its formative basic science at CSIRO and the Victorian College of Pharmacy to its manufacture in Boronia, Victoria, zanamivir (Relenza) is an original Australian product.

Zanamivir was the first of a new class of anti-viral drugs, known as neuraminidase inhibitors, capable of treating or preventing infection from the influenza virus. Neuraminidase is an essential enzyme for all influenza viruses and allows new viruses to be released from infected lung cells.

Relenza is used by inhalation and is delivered directly to the respiratory tract, the primary site of viral infection and replication. The drug works by blocking the replication and the spread of the virus.

Relenza is an anti-viral, used to treat and prevent infection from influenza. It is not a vaccine.

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 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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Issued: Wednesday 22 July, London UK

Pandemic (H1N1) 2009 Influenza Update

GlaxoSmithKline (GSK) today issued an update on its progress to support governments and health authorities around the world respond to pandemic (H1N1) 2009 influenza.

Since the outbreak of the virus, GSK has shared resources and data with many authorities and governments around the world to help improve vigilance, understanding and potential responses to the virus. The company has also worked closely with the World Health Organisation (WHO) and acknowledges the leadership it has shown throughout the advancement of the pandemic.

The company has several interventions of value to help protect populations against the H1N1 influenza virus. Following more than ten years of investment in research and development of pandemic influenza vaccines, and the successful registration of its pre-pandemic H5N1 vaccine, the company is making rapid progress to produce an A (H1N1) adjuvanted influenza vaccine.

GSK has also significantly increased production levels of its anti-viral influenza treatment *Relenza* and developed an innovative respirator mask, designed to protect the wearer from inhaling airborne influenza virus.

GSK is committed to facilitating equitable access to all these interventions to all countries. The company strongly endorses the principles set out by the Gates Foundation to help guide global allocation of pandemic vaccines and reiterates that the global community should take all steps necessary to protect all populations, including those without resources to protect themselves.

Pandemic (H1N1) 2009 adjuvanted vaccine development

Following receipt of the virus strain at the end of May, GSK started production of an H1N1 adjuvanted vaccine and is working to ensure that the vaccine is made available as quickly as possible. Manufacture of the vaccine is dependent upon certain conditions, including yield of the influenza strain supplied by the WHO for production of antigen. As the WHO and other manufacturers have indicated the first series of strains generated for this H1N1 virus are producing relatively low yields. The WHO laboratory network is generating further strains that may provide higher yields.

The candidate vaccine will consist of two vials – pandemic (H1N1) 2009 antigen and the company's AS03 adjuvant system, which will be combined before administration. Regulators, such as the EMEA and the FDA, will assess a generated data package including safety information, according to predefined criteria to determine approval of the vaccine.

GSK is currently in discussions with regulatory authorities to develop appropriate clinical development plans.

The total population studied in clinical trials will be limited due to the need to provide the vaccine to governments as quickly as possible. Additional studies will therefore be required and conducted after the vaccine is made available.

GSK strongly supports the WHO's call for post-marketing surveillance of the 'highest possible quality' to ensure extensive safety evaluation of all pandemic vaccines. GSK will rapidly share results of immunogenicity and post-marketing safety and effectiveness studies among the international community.

Adjuvant technology

In clinical studies using the avian influenza H5N1 strain, use of the AS03 adjuvant in the GSK vaccine was shown to stimulate a higher immune response while using a smaller amount of antigen as compared to a formulation without adjuvant.ⁱ This finding, known as antigen sparing, helps to increase the number of vaccine doses that can be produced. In addition, cross protection against different avian influenza strains was observed in those clinical trials.ⁱⁱ

GSK has produced clinical data relating to its AS03 adjuvant technology and has received regulatory approvals in the European Union and some Asian countries for its pre-pandemic and pandemic H5N1 vaccines, both of which contained the AS03 adjuvant. Clinical trials in over 39,000 people have demonstrated that the AS03 adjuvant system used with an influenza vaccine has an acceptable safety and reactogenicity profile. Clinical trials are ongoing to generate additional data.

GSK has made substantial investments to expand capacity for its adjuvant system and stands ready to work with governments and regulatory agencies that may decide to combine the adjuvant system with alternatively sourced antigen.

Allocation and supply

GSK is in active discussions with more than 50 governments of both developed and developing countries, for supplies of the vaccine.

The company is on track to meet the vaccine orders placed so far by governments and to supply the WHO with an intended donation of 50 million doses of its H1N1 vaccine. So far, GSK has received orders for 195 million doses of the vaccine and first supplies of the vaccine will be available to governments from September onwards. Shipments are expected in both 2009 and 2010 and the pace of delivery will be dependant on capacity and the yield of the influenza strain.

To further ensure that the vaccine is available to developing nations, and subject to the yield and existing contractual commitments, GSK has allocated 20% of production at its Canadian manufacturing site to developing countries from early September onwards. Included within this capacity is GSK's proposed donation of 50 million doses of the H1N1 vaccine to the WHO. Ongoing discussions with developing country governments may well lead to an increase in the percentage of output supplied to developing countries.

GSK is operating a tiered-pricing policy for its vaccine, based on World Bank classification of countries and GAVI eligibility.

***Relenza* (zanamivir) anti-viral treatment production**

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

Clinical tests have confirmed that pandemic (H1N1) 2009 is sensitive to inhibitors of neuraminidase such as Tamiflu and *Relenza*. Following the outbreak, GSK has contacted governments around the world to ascertain demand for *Relenza* and has put in place a series of measures to raise production levels. As a result, GSK now expects to increase its annual production capacity of *Relenza* to 190 million treatment courses by the end of 2009. This represents a threefold increase to GSK's previous maximum capacity of 60 million treatment courses.

This new capacity has been achieved by increasing production levels of *Relenza Diskhaler* from 60 million treatment courses to 90 million and building new capacity to produce 100 million treatment courses a year of *Relenza Rotacaps*. This alternative *Relenza* treatment was granted temporary approval by Swedish regulators earlier this month, as part of an application submitted under the European mutual recognition procedure for distribution during a pandemic. GSK is in discussions with regulatory authorities around the world to secure further approvals.

GSK has contracts in place to supply *Relenza* to over 60 governments. GSK has also allocated 10% of its new *Relenza* production capacity for developing countries. Included within this capacity is an intended donation of 2 million doses of *Relenza* to the WHO. GSK is also operating a tiered-pricing policy for *Relenza*, again based on World Bank classification of countries. In line with GSK's commitments set out in March to make our branded medicines more affordable to the world's poorest people, *Relenza* will continue to be sold at not-for-profit prices to least developed countries.

GSK remains committed to engaging in voluntary license discussions with other companies willing to manufacture and supply a *Relenza* product for use in developing countries.

***Actiprotect* anti-viral face masks**

GSK has developed *Actiprotect*, an innovative new disposable respirator mask specifically designed with a coating that has antiviral effectiveness.

The mask helps protect the wearer from exposure to airborne particles during seasonal influenza A or an influenza A pandemic virus by reducing the passage of the virus through the mask and inactivating the virus on contact with the mask coating. *Actiprotect* has not been tested against the pandemic (H1N1) 2009 strain. However, the mask has been shown to inactivate all influenza virus strains that it was tested against including previous strains of H1N1, H5N1, H5N9, H2N2, H3N2, and an influenza B strain.

Actiprotect has been approved for use in Europe and certain international markets and last month was approved for occupational use in the USA by the FDA. The mask has also been certified as an N95 respirator (filters at least 95% of airborne particles) by the US National Institute of Occupational Safety and Health.

GSK currently has limited manufacturing capacity for *Actiprotect*. The company has therefore made investments to increase its existing manufacturing capacity and is also seeking additional manufacturing capability through discussion with other companies. The company has agreements with several countries to supply the masks.

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 2008.

Registered in England & Wales:
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ⁱ Borkowski A et al. Antigen sparing effect of a novel adjuvant system in a split H5N1 pandemic vaccine. IVW 2006 oral presentation

ⁱⁱ Leroux-Roels I et al, Broad Clade 2 Cross-Reactive Immunity Induced by an Adjuvanted Clade 1 rH5N1 Pandemic Influenza Vaccine (in Press) PLoS ONE, Feb 2008