

**Biota Holdings Limited**

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Melbourne, Australia — 1 April 2011

**BARDA awards major contract to Biota**

Biota Holdings Limited (ASX:BTA) advises that the Office of Biomedical Advanced Research and Development Authority (BARDA) within the Office of the Assistant Secretary for Preparedness and Response (ASPR) at the U.S. Department of Health and Human Services (HHS) has awarded up to an estimated US\$231 million contract to its wholly owned subsidiary, Biota Scientific Management Pty Ltd, for the advanced development of laninamivir. The contract is fully funded over an estimated five (5) year period and is contingent upon the delivery of key milestones throughout the period.

The contract is designed to provide US based manufacturing and clinical data to support a New Drug Application for laninamivir, to the US Food and Drug Administration.

Biota CEO, Peter Cook, commented, "The award provides visible recognition of the potential medical value of laninamivir to the world's major market. The BARDA contract will be a major contributor to a timely introduction of the product and will create the opportunity to significantly develop Biota's business in the USA".

A copy of the U.S. Department of Health and Human Services press release is attached.

**About Laninamivir**

Laninamivir is an influenza antiviral, known as a long acting neuraminidase inhibitor (LANI) and a unique treatment for influenza. Unlike vaccines, neuraminidase inhibitors offer the ability to treat an influenza infection, but may also be used preventatively.

Current or first-generation neuraminidase inhibitors require twice daily dosing. LANI compounds are more potent, have a longer residence time in the lung and offer the potential of a single administration for treatment and once a week for prevention. This represents a significant advantage over all existing influenza antivirals.

Laninamivir is approved for sale in Japan and was launched as Inavir by Daiichi Sankyo in October 2010. It is not currently approved for sale in other markets.

## 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 co-owns with Daiichi Sankyo a range of second generation influenza antivirals, of which the lead product Inavir<sup>®</sup>, is approved for marketing in Japan.

Relenza<sup>™</sup> is a registered trademark of the GlaxoSmithKline group of companies.

Inavir<sup>®</sup> is registered to Daiichi Sankyo.

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## News Release

FOR IMMEDIATE RELEASE  
Thursday, March 31, 2011

Contact: HHS Press Office  
(202) 690-6343

### BARDA funds advanced development of new influenza antiviral

A contract has been awarded to develop a long-acting single-dose antiviral drug for use in the United States, the U.S. Biomedical Advanced Research and Development Authority (BARDA) announced today.

The drug, CS-8958, is currently marketed in Japan under the name Inavir and is in the same class of drugs as the currently approved influenza antiviral drugs Tamiflu and Relenza. CS-8958 requires only a single dose for full treatment, as opposed to the five days of twice daily dosing required for Tamiflu and Relenza. CS-8958 also may be effective against influenza viruses known to be resistant to Tamiflu.

The advanced development contract for was issued to Biota Scientific Management Pty, Ltd., of Melbourne, Australia, for \$231 million over five years.

"This award represents another critical step forward in ensuring that safe and effective antiviral drugs are available for the treatment of influenza," said BARDA Director Dr. Robin Robinson. "The ability to treat influenza by delivering a single dose of medicine would provide real advantages to doctors and patients during an emergency and would be an important addition to our pandemic influenza arsenal."

CS-8958 is a long-acting neuraminidase inhibitor, which prevents the flu virus from spreading in the body's cells. The drug is delivered using a dry powder inhaler.

Under the contract, the company will establish U.S. manufacturing of the drug, optimize its manufacturing processes, and conduct clinical trials for safety and efficacy in adult and pediatric populations. These studies are needed to apply for U.S. Food and Drug Administration approval of the drug.

The contract is part of BARDA's implementation of the national pandemic influenza preparedness strategy, which includes accelerating the advanced development of new antiviral drugs.

BARDA, an agency within the Office of the Assistant Secretary for Preparedness and Response in the U.S. Department of Health and Human Services, provides a comprehensive, integrated, portfolio approach to the advanced research and development, innovation, acquisition, and manufacturing infrastructure for vaccines, drugs, therapeutics, diagnostic tools, and non-pharmaceutical products for public health emergency threats. These threats include chemical, biological, radiological, and nuclear threats, pandemic influenza, and emerging infectious diseases.

For more information about BARDA and the national influenza preparedness strategy, visit [www.phe.gov](http://www.phe.gov). Information about the flu is available at [www.flu.gov](http://www.flu.gov).

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Note: All HHS press releases, fact sheets and other press materials are available at <http://www.hhs.gov/news>.

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