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## Inavir® approved for sale in Japan

Biota Holdings Limited (ASX:BTA) today announced that Daiichi Sankyo has received approval to manufacture and market Inavir<sup>®</sup> (pronounced in-a-veer) in Japan. Inavir<sup>®</sup> is Daiichi Sankyo's brand of laninamivir octanoate and also previously known as CS-8958. The approved indication is for the treatment of influenza in adults and children.

Inavir<sup>®</sup> (laninamivir octanoate), is the first drug of a new class of long acting neuraminidase inhibitors (LANIs) to address the limitation of the current products, which require daily or more frequent dosing. Neuraminidase inhibitors (NIs) are antiviral agents effective against influenza, providing both for the treatment of an established influenza infection or for the prevention of influenza prior to exposure. NIs are antiviral medicines and are not vaccines.

The new class of long acting neuraminidase inhibitors provide the opportunity to medicate patients on a "one and done" basis and offer a number of potential benefits. These include that the patient is more likely to use the product properly and as intended and also offers a reduced cost of storage and transport per course, where the product is intended to be stockpiled.

In 2003, Biota and Daiichi Sankyo merged their respective LANI programs. Under the co-ownership agreement, Daiichi Sankyo held an option to manufacture and sell laninamivir in Japan, in return for funding an extensive range of Japanese clinical trials. Under the agreement, Biota will receive a royalty on all sales in Japan and may also qualify for certain sale's milestone payments.

Daiichi Sankyo and Biota have been in discussion with a number of suitable companies for the licensing of laninamivir in the rest of world. Those discussions are continuing. The Companies are confident that laninamivir will prove to be a valuable therapeutic product with many patient and community advantages.

A copy of the Daiichi Sankyo announcement is attached.

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#### **About Daiichi Sankyo**

The Daiichi Sankyo Group is dedicated to the creation and supply of innovative pharmaceutical products to address the diversified, unmet medical needs of patients in both mature and emerging markets. While maintaining its portfolio of marketed pharmaceuticals for hypertension, hyperlipidemia, and bacterial infections, the Group is engaged in the development of treatments for thrombotic disorders and focused on the discovery of novel oncology and cardiovascular-metabolic therapies. Furthermore, the Daiichi Sankyo Group has created a "Hybrid Business Model," which will respond to market and customer diversity and optimize growth opportunities across the value chain. For more information, please visit www.daiichisankyo.com

#### **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 lnavir, is approved for marketing in Japan.

Relenza $^{\text{TM}}$  is a registered trademark of the GlaxoSmithKline group of companies. \*Further information available at <a href="www.biota.com.au">www.biota.com.au</a>

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# Daiichi Sankyo Receives Approval to Manufacture and Market Inavir<sup>®</sup> Influenza Antiviral Inhalant for Treatment in Japan

**Tokyo, Japan (September 10, 2010)** – Daiichi Sankyo Company, Limited (hereafter, Daiichi Sankyo), today announced that it has received approval in Japan to manufacture and market Inavir<sup>®</sup> Dry Powder Inhaler 20mg, for treatment of influenza that is a laninamivir octanoate hydrate prodrug.

Inavir<sup>®</sup> is a long-acting neuraminidase inhibitor that Daiichi Sankyo developed for the Japanese market. Inavir<sup>®</sup> directly delivers the drug to the infected airways of influenza patients, and a single inhaled dose has proven to be as effective as a five-day course of oseltamivir for treatment of influenza. The company is confident that Inavir<sup>®</sup> will be an important alternative for treating influenza, both benefiting patients and contributing to society.

Daiichi Sankyo has a solid record in developing and selling antibacterial agents, and also offers influenza vaccines. Inavir® complements the company's lineup for preventing and treating primary and secondary influenza infections.

### Inavir® Overview

Product name	Inavir® Dry Powder Inhaler 20mg
Generic name	Laninamivir (International Nonproprietary
	Names)
Indication	Treating influenza A and B viruses
Dosage and Administration	Adults: A single inhaled dose of 40 mg of
	laninamivir octanoate hydrate
	Children: If less than 10 years old, a single
	inhaled dose of 20 mg of laninamivir
	octanoate hydrate. If 10 years old or older, a
	single inhaled dose of 40 mg.
Approval date	September 10, 2010