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### Daiichi Sankyo submits a New Drug Application in Japan for CS-8958

Biota Holdings Limited (ASX:BTA) today advised that a New Drug Application in Japan had been filed for CS-8958 by its co-owner Daiichi Sankyo.

A copy of the Daiichi Sankyo release is attached.

## **About Daiichi Sankyo**

A global pharmaceutical innovator, Daiichi Sankyo Co., Ltd., was established in 2005 through the merger of two leading Japanese pharmaceutical companies. Daiichi Sankyo discovered CS-8958.

#### **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 novel nucleoside analogues designed to treat hepatitis C virus (HCV) infections, licensed to Boehringer Ingelheim, and a series of candidate drugs aimed at treatment of respiratory syncytial virus (RSV) disease. Biota has clinical trials underway with its lead compound for human rhinovirus (HRV) infection in patients with compromised respiration or immune systems.

Biota and Daiichi Sankyo have pooled their respective intellectual property for the development of second generation influenza anti-virals whereby Biota will receive royalties on sales of CS-8958 by Daiichi Sankyo in Japan. In addition, Biota and Daiichi Sankyo are seeking a commercial partner for CS-8958 for the Rest of the World and for which the co-owners will share the commercial returns.

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

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Daiichi Sankyo Submits a New Drug Application in Japan for CS-8958, a Long-Acting Neuraminidase Inhibitor for the Treatment of Influenza

Tokyo, Japan (February 1, 2010) – Daiichi Sankyo Company, Limited (hereafter; Daiichi Sankyo), today announced that it has submitted a New Drug Application to the Ministry of Health, Labor and Welfare for approval in Japan of CS-8958, a proprietary anti-flu drug.

CS-8958 is a laninamivir prodrug that is a Long-Acting Neuraminidase Inhibitor. The drug, developed entirely for the Japanese market by Daiichi Sankyo, will be in the form of an inhalant that will directly treat the airways of influenza patients. Clinical studies to date with adults and children suffering from type A or B influenza viruses have proven CS-8958 to be effective with a single administration.

In non-clinical studies, CS-8958 has also demonstrated that it is efficacious with the H1N1 and potentially lethal H5N1 (avian influenza) viruses, leading to an expectation for wide-ranging contributions to influenza treatment in the future.

In November 2009, Daiichi Sankyo began a Phase III clinical study in Japan on the prophylactic use of CS-8958.