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Eisai Co., Ltd.

EISAI ENTERS INTO JAPAN CO-PROMOTION AGREEMENT WITH NOVARTIS PHARMA FOR COPD THERAPIES

Eisai Co., Ltd. (Headquarters: Tokyo, President & CEO: Haruo Naito, "Eisai") announced today that it has entered into a Japan co-promotion agreement with Novartis Pharma K.K. (Headquarters: Tokyo, President & CEO: Hiroyuki Mitani, "Novartis Pharma") for three Novartis Pharma therapies for chronic obstructive pulmonary disease (COPD). These include Onbrez® Inhalation Capsules 150 mcg (indacaterol maleate), which were launched in Japan on September 20, 2011, and, if approved, the investigational drugs NVA237 (glycopyrronium bromide) and QVA149 (fixed-dose combination of indacaterol maleate and glycopyrronium bromide), both of which are currently in Phase III development.

Based on this agreement, the two companies will begin co-promoting Onbrez® on December 1, 2011. While Novartis Pharma will concentrate its promotional activities on university and flagship hospitals, Eisai will target other healthcare providers including general hospitals and primary care physicians. The manufacture and sale of Onbrez® will be handled by Novartis Pharma in the same way as before, with the two companies commencing co-promotion of NVA237 and QVA149 following their launch.

The new co-promotion agreement is a partnership of mutual commitment between Eisai and Novartis Pharma. Novartis Pharma aims to maximize the value of Onbrez®, a new long-acting bronchodilator that provides sustained 24-hour efficacy and has a rapid onset of action at first dose, as well as NVA237 and QVA149, which combines indacaterol together with NVA237, while Eisai seeks to further enhance its product portfolio in the area of internal medicine.

COPD is a chronic, progressive lung disease that is commonly caused by the long-term inhalation of cigarette smoke or other harmful substances, which results in symptoms such as coughing, sputum production and breathlessness. The disease significantly reduces the quality of life of patients, and can be potentially life-threatening due to the gradual progression of symptoms that eventually lead to respiratory failure. Although the latest figures show only 173,000 people have been diagnosed with COPD in Japan[1], epidemiological data shows that the total number of patients could be as high as 5.3 million[2], which suggests that there are many patients with untreated COPD.

With the conclusion of the co-promotion agreement, Eisai and Novartis seek to establish a greater presence in the field of COPD and achieve a synergistic effect, thereby making further contributions to address the unmet needs of, and increase the benefits provided to, COPD patients.

[Please refer to the following notes for further information on Onbrez®, NVA237 and QVA149]

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[Notes to editors]

1. About Onbrez®

Onbrez® was developed by Novartis International AG, a multinational pharmaceutical company headquartered in Switzerland, and is currently approved in more than 70 countries worldwide. Launched in Japan on September 20 of this year, Onbrez® is the only long-acting β_2-agonist (LABA) for the treatment of COPD to combine 24-hour sustained broncodilation[5,6,7] from a once-daily dose with a rapid onset of action within five minutes of inhalation[3,4].

【Product Outline】

Product Name:	Onbrez® Inhalation Capsules 150 mcg
Generic Name:	Indacaterol maleate
Indications and Usage:	Relief of various symptoms associated with airflow obstruction in patients with chronic obstructive pulmonary disease (chronic bronchitis, emphysema).
Dosage and Administration:	The recommended adult dose of indacaterol maleate is the inhalation of the content of one 150 mcg capsule once a day, using an inhaler for use exclusively with Onbrez.
Date of Approval:	July 1, 2011
Date of Listing on the National Health Insurance Drug Reimbursement Price List:	September 12, 2011
Price:	139.60 yen per 150 mcg capsule
Date of Launch:	September 20, 2011
Manufactured by:	Novartis Pharma K.K.
Co-promoted by:	Eisai Co., Ltd.

2. About NVA237 and QVA149

NVA237 is a long-acting muscarinic antagonist (LAMA) being developed as a COPD treatment for once-daily inhalation. In Japan, it is currently undergoing Phase III clinical trials. NVA237 was licensed to Novartis in April 2005 by Vectura Group plc and its co-development partner Sosei Group Corporation. Novartis holds the exclusive worldwide rights to develop and market the drug.

QVA149 is a combination of Onbrez®, a LABA, and NVA237, a LAMA, and is being developed as a COPD treatment for once-daily inhalation. In Japan, the drug is currently undergoing Phase III clinical trials.

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3. Balint B, Watz H, Amos C, et al. Onset of action of indacaterol in patients with COPD: Comparison with salbutamol and salmeterol-fluticasone. Int J Chron Obstruct Pulmon Dis 2010;5:311-318.
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5. Donohue JF, Fogarty C, Lötvall J, et al. Once-daily bronchodilators for chronic obstructive pulmonary disease: Indacaterol versus tiotropium. Am J Respir Crit Care Med 2010;182:155-162.
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