For immediate release

Company name: DAIICHI SANKYO COMPANY, LIMITED
Representative: Joji Nakayama, President and CEO
(Code no.: 4568, First Section of Tokyo, Osaka and Nagoya Stock Exchanges)
Please address inquiries to Noriaki Ishida, Corporate Officer,
Vice President, Corporate Communications Department
Telephone: +81-3-6225-1126
http://www.daiichisankyo.com

Daiichi Sankyo Enrolls First Patient in Nimotuzumab Phase 3 Clinical Trials

Tokyo, Japan (April 25, 2013) – Daiichi Sankyo Company, Limited (hereafter, Daiichi Sankyo) announced today that the first patient has been enrolled in two pivotal phase 3 clinical trials of nimotuzumab (DE-766), a recombinant humanized monoclonal antibody targeting the Epidermal Growth Factor Receptor (EGFR), which is being evaluated for the treatment of patients diagnosed with lung cancer and with gastric cancer.

About Phase 3 Clinical Trials for Lung Cancer

The phase 3 clinical trial is a multicenter, randomized, double-blind, placebo-controlled study investigating nimotuzumab for the first-line therapy in patients with unresectable and locally advanced squamous cell lung cancer. The patients will receive either nimotuzumab in combination with concurrent chemoradiotherapy or placebo in combination with concurrent chemoradiotherapy. The primary endpoint is overall survival (OS), and the secondary endpoints are progression free survival (PFS) and safety. Approximately 420 patients are planned to be enrolled at approximately 60 clinical centers in Japan. Additional details of the trial are available on www.clinicaltrials.jp/user/cteSearch.jsp.

About Phase 3 Clinical Trials for Gastric Cancer (ENRICH study)

The ENRICH study is a randomized, open-label, Japan-Korea collaborative study of previously treated patients with EGFR overexpressed advanced gastric and gastroesophageal junction cancer who will receive either nimotuzumab and irinotecan hydrochloride hydrate (hereafter, irinotecan) combination therapy or irinotecan monotherapy. The primary endpoint is overall survival (OS), and the secondary endpoints are progression free survival (PFS) and safety. Approximately 400 patients are planned to be enrolled at approximately 40 clinical centers in Japan and South Korea. In Korea, Kuhnil Pharmaceutical Company, Limited (hereafter, Kuhnil) is implementing this trial. Additional details of the trial are available on www.clinicaltrials.gov.

About Unresectable and Locally Advanced Squamous Cell Lung Cancer

In Japan, lung cancer is the first leading cause of cancer death, with about 70,000 deaths in 2011.[i] Non-small cell lung cancer (adenocarcinoma, squamous cell carcinoma, and large cell carcinoma)

occupies more than 80 percent of lung cancer. Concurrent chemoradiotherapy for a radical cure is currently used as the standard treatment for patients with stage III locally advanced non-small cell lung cancer, in which radical surgery is not possible but radiotherapy is.[ii] Of these cases, between 30 and 40 percent are squamous cell carcinoma and EGFR is known to be overexpressed.[iii]

About Gastric Cancer

Half of the total number of gastric cancer cases worldwide occurs in Eastern Asia.[iv] In Japan, gastric cancer is the second leading cause of cancer death, with an estimated about 50,000 deaths.[i] In South Korea, about 10,000 gastric cancer deaths in 2011 were reported.[v] Numerous improvements have occurred in the management of gastric cancer; however, gastric cancer still has a poor prognosis. For patients with earlier stages of disease, more than 50% undergo surgery, but even after a curative resection, 60% of these patients eventually relapse locally or with distant metastases.[vi]

About Nimotuzumab and EGFR

Nimotuzumab is an intravenously administered recombinant humanized monoclonal antibody directed against human EGFR and is produced by CIMAB S.A. (Cuba). Nimotuzumab blocks the binding of EGF to its receptor interfering with the cell signaling pathway. Nimotuzumab has been approved for head and neck cancer, glioma, and esophageal cancer in several countries. EGFR is known to be overexpressed in a wide variety of human tumors.[vii] Overexpression of EGFR in tumors correlates with increased metastasis, decreased survival, and a poor prognosis. It is known that EGFR is activated by exposure to radiation.

In 2006, Daiichi Sankyo introduced nimotuzumab from CIMAB S.A. and CIMYM BioSciences Inc. (Canada) and has the rights to develop and commercialize in Japan. In Korea, Kuhnil has the rights to develop and commercialize.

Reference

i) Vital Statistics of Japan (Ministry of Health, Labour and Welfare); 2011.

ii) Lung Cancer Clinical Practice Guidelines (Japan Lung Cancer Society); 2012.

iii) Ito T, Ishii G, Nagai K, et al. Low podoplanin expression of tumor cells predicts poor prognosis in pathological stage IB squamous cell carcinoma of the lung, tissue microarray analysis of 136 patients using 24 antibodies. Lung Cancer 2009; 63(3):418–424.

iv) ESTIMATEN CANCER INCIDENCE: GLOBOCAN 2008 [Internet]. International Agency for Research on Cancer [ver.1.2, cited Dec 2010]. Available from: http://globocan.iarc.fr/

v) National Cancer Information Center [Internet]. Available from http://www.cancer.go.kr/mbs/cancer/subview.jsp?id=cancer_100100000000

vi) Ajani JA. Evolving chemotherapy for advanced gastric cancer. The Oncologist. 2005;10(3):49-58.

vii) Salomon DS, Brandt R, Ciardiello F, et al. Epidermal growth factor-related peptides and their receptors in human malignancies. Crit Rev Oncol Hematol 1995; 19:183-232.