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Daiichi Sankyo Announces Discontinuation of Phase 3 Clinical Trial in Japan of Nimotuzumab (DE-766) in Lung Cancer

TOKYO, Japan (April 25, 2014) - Daiichi Sankyo Company, Limited announced today the discontinuation of the phase 3 clinical trial conducted in Japan for nimotuzumab (DE-766) in Lung Cancer.

The phase 3 clinical trial was a multicenter, randomized, double-blind, placebo-controlled study investigating nimotuzumab for first-line therapy in patients with unresectable and locally advanced squamous cell lung cancer. Patients received either nimotuzumab in combination with concurrent chemoradiotherapy or a placebo in combination with concurrent chemoradiotherapy.

The study was discontinued based on the recent recommendation of the Independent Data Monitoring Committee which observed safety issues in certain patients who received a combination of cisplatin, vinorelbine, radiotherapy, and nimotuzumab.

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 Nimotuzumab and EGFR

Nimotuzumab is an intravenously administered recombinant humanized monoclonal antibody directed against human Epidermal Growth Factor Receptor (EGFR) and is produced by CIMAB S.A. (Cuba). nimotuzumab blocks the binding of Epidermal Growth Factor (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 and used in 29 completed and 26 on-going trials worldwide without any major safety concern so far. EGFR is known to be overexpressed in a wide variety of human tumors.^{iv} 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.

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) 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.