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Results of the J-ALEX Study for Chugai's Alecensa® are Published in "The Lancet" Online

- Following the Publication in "The Lancet Oncology" of Japanese PI/II Study, Japanese PIII Study is also Published in Authoritative Scientific Journal -

TOKYO, May 11, 2017 -- Chugai Pharmaceutical Co., Ltd. (TOKYO: 4519) announced today that the results of the Japanese phase III study (J-ALEX) of Alecensa®, in patients with *ALK* fusion gene positive non-small cell lung cancer (NSCLC), were published in the electronic version of "The Lancet" on May 10, 2017.
http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(17)30565-2/fulltext

The initial results of the J-ALEX study were presented at a session of the American Society of Clinical Oncology (ASCO) meeting held in Chicago, on June 6, 2016.

"The publication of the J-ALEX study results in 'The Lancet' assures the firm position of Alecensa in the first line therapy of patient with *ALK* fusion gene positive NSCLC," said Dr. Yasushi Ito, Senior Vice President, Head of Project & Lifecycle Management Unit. "We believe that Alecensa will also contribute to improving the outcomes for patients in first line therapy, as well as second line therapy in the future."

The J-ALEX study was an open-label, randomized phase III study that compares the efficacy and safety between Alecensa and crizotinib. The J-ALEX study enrolled 207 ALK-inhibitor naïve patients with *ALK* fusion gene positive advanced or recurrent NSCLC, who either had not undergone chemotherapy or had undergone one chemotherapy regimen. The primary endpoint of the J-ALEX study was progression free survival (PFS) as assessed by an independent review board. The secondary endpoints included overall survival, objective response rate, safety, and other endpoints.

The PFS hazard ratio of the Alecensa arm to the crizotinib arm was 0.34 (99.7% CI: 0.17-0.71, stratified log-rank p<0.0001) and Alecensa demonstrated significantly prolonged PFS. Median PFS was not reached (95% CI: 20.3-Not Estimated) in the Alecensa arm while it was 10.2 months (95%CI: 8.2-12.0) in the crizotinib arm. In the Alecensa arm, constipation (35%) was an adverse event (AE) with >30% frequency, while in the crizotinib arm nausea (74%), diarrhea (73%), vomiting (58%), visual disturbance (55%), dysgeusia (52%), constipation (44%), ALT elevation (32%), and AST elevation (31%) were each seen in >30% patients. Grade 3-4 AEs occurred in 26% of the Alecensa arm and in 52% of the crizotinib arm, there were no treatment-related deaths in either arm.

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In February 2016, Chugai carried out a prospectively-defined interim analysis and had an independent data monitoring committee examine the results. Since the results showed that the Alecensa arm significantly prolonged the PFS, the committee decided to recommend an early discontinuation of the J-ALEX study.

Based on the results of the J-ALEX study, Alecensa was granted Breakthrough Therapy Designation by the U.S. Food and Drug Administration in September 2016 for first line therapy of patients with ALK-positive non-small cell lung cancer.

About Chugai

Chugai Pharmaceutical is one of Japan's leading research-based pharmaceutical companies with strengths in biotechnology products. Chugai, based in Tokyo, specializes in prescription pharmaceuticals and is listed on the 1st section of the Tokyo Stock Exchange. As an important member of the Roche Group, Chugai is actively involved in R&D activities in Japan and abroad. Specifically, Chugai is working to develop innovative products which may satisfy the unmet medical needs, mainly focusing on the oncology area.

In Japan, Chugai's research facilities in Gotemba and Kamakura are collaborating to develop new pharmaceuticals and laboratories in Ukima are conducting research for technology development for industrial production. Overseas, Chugai Pharmabody Research based in Singapore is engaged in research focusing on the generation of novel antibody drugs by utilizing Chugai's proprietary innovative antibody engineering technologies. Chugai Pharma USA and Chugai Pharma Europe are engaged in clinical development activities in the United States and Europe.

The consolidated revenue in 2016 of Chugai totalled 491.8 billion yen and the operating income was 80.6 billion yen (IFRS Core basis).

Additional information is available on the internet at https://www.chugai-pharm.co.jp/english.

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