



Chugai's ALK Inhibitor "Alecensa[®]" Trial Stopped Early for Benefit - Demonstrates Statistically Significant Improvement in PFS in a Japanese Phase III Head to Head Study with Crizotinib -

TOKYO, February 10, 2016 - Chugai Pharmaceutical Co., Ltd. (TOKYO: 4519) announced that it received a recommendation by an independent data monitoring committee (IDMC) that the J-ALEX Study, a phase III study targeting *ALK* fusion gene positive non-small cell lung cancer (NSCLC) being conducted in Japan, should be stopped early as the study met its primary endpoint at a pre-planned interim analysis. The study showed that patients lived significantly longer without disease worsening (progression-free survival, PFS) when treated with Alecensa[®] compared to crizotinib.

The J-ALEX study is an open-label, randomized phase III study that compares the efficacy and safety between Alecensa and crizotinib. The J-ALEX study enrolled 207 patients with *ALK* fusion gene positive advanced or recurrent NSCLC who either had not undergone chemotherapy or had undergone one chemotherapy regimen. The subjects were allocated to the Alecensa group or the crizotinib group in a one to one ratio.

Chugai carried out a prospectively defined interim analysis of the J-ALEX study, and had an IDMC examine the results. Since the results showed that Alecensa significantly prolonged the PFS to a higher extent than anticipated, the committee decided to recommend an early discontinuation of the study, as described above. The safety issues of Alecensa have not been pointed out. The data of the J-ALEX study will be presented at a future medical meeting, etc.

"The fact that the J-ALEX study received a recommendation by an IDMC to be stopped early due to positive effects is great news, and a blessing for the patients who are involved in the study." said Chugai's Director and Executive Vice President, Dr. Yutaka Tanaka. "We are extremely happy that these results can offer hope and encouragement to patients in need to be treated with Alecensa."

As a top pharmaceutical company in the field of oncology in Japan, Chugai believes that early treatment using Alecensa in *ALK* fusion gene positive NSCLC is expected not only to prolong these patients' PFS, but also enable them to face their disease with a positive hope for the future.

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 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 2015 of Chugai totalled 498.8 billion yen and the operating income was 90.7 billion yen (IFRS Core basis).

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

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