



Final Progression-Free Survival Data and the Second Interim Analysis of Overall Survival from the J-ALEX Study for Alecensa Presented at the 2019 American Society of Clinical Oncology (ASCO) Annual Meeting

- Alecensa reduced the risk of disease progression or death by 63% compared to crizotinib
- Long-term follow-up reconfirmed that Alecensa prolonged progression-free survival compared to crizotinib

TOKYO, June 3, 2019-- [Chugai Pharmaceutical Co., Ltd.](#) (TOKYO: 4519) announced that the final progression-free survival (PFS) data and the second interim analysis of overall survival (OS) from the Japanese phase III J-ALEX study for Alecensa® were presented on June 2 (local time) at the 2019 American Society of Clinical Oncology (ASCO) Annual Meeting, taking place from May 31 to June 4 in Chicago, IL, United States. J-ALEX study compared Alecensa and crizotinib as the first-line treatment for patients with *ALK* fusion gene positive non-small cell lung cancer (NSCLC).

Abstract #9092;

Final PFS analysis and safety data from the phase III J-ALEX study of Alectinib (ALC) vs. Crizotinib (CRZ) in *ALK*-inhibitor naïve *ALK*-positive Non-Small Cell Lung Cancer (*ALK*+NSCLC)

“The long-term data from the J-ALEX study confirms the benefits of Alecensa as the first-line treatment for patients with *ALK*-positive NSCLC,” said Dr. Yasushi Ito, Chugai’s Executive Vice President, Co-Head of Project & Lifecycle Management Unit.

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 *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 PFS as assessed by an independent review facility (IRF). The secondary endpoints included OS, time to disease progression of brain metastases in patients with brain metastases at baseline, and safety.

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 Alecensa significantly prolonged PFS to a higher extent than anticipated, the committee decided to recommend an early discontinuation of the study [Alecensa arm: not estimable (95% CI: 20.3-not estimable), crizotinib arm: 10.2 months (95% CI: 8.2-12.0), HR=0.34 (99.7% CI: 0.17-0.70), stratified log-rank test, $p<0.0001$].

Latest data from the J-ALEX study shows:

- Risk of progression or death was reduced by 63% (HR=0.37, 95% CI: 0.26-0.52) in the Alecensa arm compared to the crizotinib arm. Median PFS (primary endpoint) was 34.1 months in the Alecensa arm (95% CI: 22.1-not estimable) versus 10.2 months (95% CI: 8.3-12.0) in the crizotinib arm.
- In the second interim analysis, the superiority of OS in the Alecensa arm over the crizotinib arm was not conclusive (stratified HR=0.80, 95% CI: 0.35-1.82). The investigation on OS will be continued.
- The safety profile of Alecensa was consistent with previous reports.

[Reference information]

Media release issued by Chugai on May 11, 2017:

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

https://www.chugai-pharm.co.jp/english/news/detail/20170511113001_82.html

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

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Contact

For Media

Chugai Pharmaceutical Co., Ltd.

Media Relations Group, Corporate Communications Dept.,

Tomoko Shimizu

Tel: +81-3-3273-0881

E-mail: pr@chugai-pharm.co.jp

For US media

Chugai Pharma USA Inc.

Casey Astringer

Tel: +1-908-516-1350

E-mail: pr@chugai-pharm.com

For European media

Chugai Pharma U.K. Ltd.

Carter Westwood

Tel: +44-20-8987-5680

E-mail: pr@chugai.eu

For Taiwanese media
Chugai Pharma Taiwan Ltd.
Susan Chou
Tel: +886-2-2715-2000
E-mail: pr@chugai.com.tw

For Investors
Chugai Pharmaceutical Co., Ltd.
Investor Relations Group, Corporate Communications Dept.,
Toshiya Sasai
Tel: +81-3-3273-0554
E-mail: ir@chugai-pharm.co.jp

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