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Chugai's ALK Inhibitor "Alecensa®" Approved for the Treatment of First Line Therapy on ALK-Positive Non-Small Cell Lung Cancer in Taiwan

- Alecensa Now Available in Taiwan at an Early Stage -

TOKYO, May 16, 2018 -- Chugai Pharmaceutical Co., Ltd. (TOKYO: 4519) announced that Chugai Pharma Taiwan Ltd., a wholly owned subsidiary of Chugai, obtained approval from the Taiwan Food and Drug Administration (TFDA), for "Alecensa®," anaplastic lymphoma kinase (ALK) inhibitor, for the treatment of "patients with ALK-positive, advanced non-small cell lung cancer (NSCLC)."

"The results of the J-ALEX study conducted by Chugai and the ALEX study conducted overseas showed that Alecensa will greatly contribute to the treatment of patients who receive at an early stage." said Dr. Yasushi Ito, Chugai's Senior Vice President, Co-Head of Project & Lifecycle Management Unit. "Following approval for first line treatment in the US and the EU in 2017, it is a great pleasure for Chugai that Alecensa has been approved for primary treatment in Taiwan followed by Japan and South Korea in the Asia region."

This approval is based on results from the phase III ALEX study. The ALEX study evaluates the efficacy and safety of Alecensa compared with crizotinib in people with ALK-positive NSCLC who had not received prior systemic therapy (first-line).

In the study, Alecensa significantly reduced the risk of disease worsening or death by 47% (primary endpoint, HR=0.53, 95%CI: 0.38-0.73, stratified log-rank test, p<0.0001) compared to crizotinib as assessed by independent review committee. Median progression-free survival (PFS) was 25.7 months (95%CI: 19.9-not estimable) for people who received Alecensa compared with 10.4 months (95%CI: 7.7-14.6) for people who received crizotinib.

The safety profile of both drugs was consistent with that observed in previous studies, with no new findings.

In addition, Alecensa significantly reduced the risk of the cancer spreading to or growing in the brain or central nervous system (CNS) compared to crizotinib by 84% (HR=0.16, 95%CI: 0.10-0.28, stratified log-rank test, p<0.0001). This was based on a time to CNS progression analysis in which there was a lower risk of progression in the CNS as the first site of disease progression for people who received Alecensa (12%) compared to people who received crizotinib (45%).

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About Alecensa

Alecensa is a highly selective oral ALK inhibitor created by Chugai. Outside of Japan, Alecensa is currently approved in the United States, Europe, Kuwait, Israel, Hong Kong, Canada, South Korea, Switzerland, India, Australia, Singapore, Taiwan, Thailand, Liechtenstein, Argentina, United Arab Emirates, Saudi Arabia and Turkey for the treatment of people with metastatic (advanced) ALK-positive NSCLC whose disease has worsened after, or who could not tolerate treatment with, crizotinib and in the US, EU, Australia, Turkey, Switzerland and South Korea for the treatment of first line therapy on ALK-positive metastatic NSCLC.

In Japan, Alecensa is available to patients with "*ALK* fusion gene positive unresectable, recurrent/advanced NSCLC" and is marketed by Chugai. The approved dosage and administration in Japan is "300mg alectinib administered orally twice daily for adult patient."

Note: The dosage and administration of the ALEX study is "600mg alectinib administered orally twice daily," which is different from the Japanese dosage and administration.

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 2017 of Chugai totaled 534.2 billion yen and the operating income was 103.2 billion yen (IFRS Core basis).

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

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