Innovation all for the patients

CHUGAI

Roche A member of the Roche group

Updated Data of Overall Survival and Safety from the ALEX Study for Chugai's Alecensa Presented at the 2020 American Society of Clinical Oncology (ASCO)

- Alecensa shows a clinically meaningful benefit in overall survival compared with crizotinib (The 5-year survival rate was 62.5% in Alecensa arm and 45.5% in crizotinib arm)
- No new safety concerns were identified, safety for Alecensa was consistent with the known safety profile

TOKYO, May 29, 2020-- Chugai Pharmaceutical Co., Ltd. (TOKYO: 4519) announced that updated data from the global phase III study (the ALEX study) for Alecensa® was presented on May 29 (local time) at the 2020 American Society of Clinical Oncology (ASCO) Virtual Scientific Program. The ALEX study compared Alecensa and crizotinib as the first-line therapy for patients with *ALK* fusion gene positive non-small cell lung cancer (NSCLC).

Abstract #9518;
Updated overall survival (OS) and safety data from the randomized, phase III ALEX study of alectinib (ALC) versus crizotinib (CRZ) in untreated advanced *ALK*+ NSCLC
https://meetinglibrary.asco.org/record/190248/abstract

Dr. Osamu Okuda, Chugai's President and COO, said "This five-year follow-up data from the ALEX study shows the long-term benefits of Alecensa as the first-line treatment of ALK-positive NSCLC. This reaffirms the position of Alecensa as one of the standard treatments."

Latest data from the ALEX study shows:

- At the updated data cut-off point, median duration of follow-up was 48.2 months (range: 0.5 - 62.7) and 23.3 months (range: 0.3 - 60.6) in the Alecensa and crizotinib arms, respectively. The number of overall survival (OS) events was 37% of the ITT population, median OS in the crizotinib arm was 57.4 months (95%CI: 34.6 – not estimable) and not estimable in the Alecensa arm (HR=0.67, 95%CI: 0.46 - 0.98). The 5-year survival rate was 62.5% (95%CI: 54.3 - 70.8) and 45.5% (95%CI: 33.6 - 57.4) in the Alecensa and crizotinib arms, respectively (secondary endpoint).
- In patients with CNS metastases at baseline, the OS hazard ratio was 0.58 (95%CI: 0.34 - 1.00) and 0.76 (95%CI: 0.45 - 1.26) in patients without CNS metastases at baseline (secondary endpoint).
- No new safety signals were observed, and the safety profile of Alecensa was consistent with previous reports.

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.

CHUGAI PHARMACEUTICAL CO., LTD. Corporate Communications Dept.
1-1, Nihonbashi-Muromachi 2-chome, Chuo-ku Tokyo, 103-8324 Japan
Media Relations Group TEL:+81-(0)3-3273-0881 E-mail:pr@chugai-pharm.co.jp
Investor Relations Group TEL:+81-(0)3-3273-0554 E-mail:ir@chugai-pharm.co.jp

[Reference information]
Media release issued by Roche on September 28, 2019:
Roche to present new and updated data at ESMO 2019 reinforcing the use of Alecensa in the first-line setting for advanced ALK-positive non-small cell lung cancer
https://www.roche.com/media/releases/med-cor-2019-09-28.htm

Media release issued by Roche on May 17, 2018:
Follow-up phase III data showed Roche's Alecensa helped people with ALK-positive metastatic non-small cell lung cancer live a median of almost three years without their disease worsening or death
https://www.roche.com/media/releases/med-cor-2018-05-17b.htm

###