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Chugai Files for Additional Indication of ALK Inhibitor ALECENSA for Recurrent or Refractory *ALK* Fusion Gene-Positive Anaplastic Large Cell Lymphoma (ALCL)

- Aim to obtain an approval for the indication of recurrent or refractory ALK-positive ALCL, using results from the investigator initiated study (the ALC-ALCL study) in pediatric and adult patients in Japan
- Alecensa obtained an orphan drug designation from the Ministry of Health, Labour and Welfare (MHLW) for the treatment of ALK-positive ALCL

TOKYO, June 3, 2019 -- [Chugai Pharmaceutical Co., Ltd.](#) (TOKYO: 4519) announced today that it filed an application for ALK Inhibitor, Alecensa® capsule 150 mg (generic name: alectinib) to MHLW for an additional indication of recurrent or refractory *ALK* fusion gene-positive anaplastic large cell lymphoma (ALK-positive ALCL). Alecensa obtained an orphan drug designation from the MHLW on May 30.

“While chemotherapy is known to be effective for ALCL, there is a strong need for development of new therapeutic options since recurrent ALCL often carries a poor prognosis,” said Dr. Yasushi Ito, Chugai’s Executive Vice President, Co-Head of Project & Lifecycle Management Unit. “We hope that we can contribute to improving prognosis of these patients with the use of Alecensa that has the possibility of becoming a promising molecular target drug for ALK-positive ALCL.”

This filing is based on the results from the investigator initiated study (the ALC-ALCL study) started in May 2015. The study has been conducted as a part of “Research Project on Practical Application of Innovative Cancer Therapy” by Japan Agency for Medical Research and Development. The ALC-ALCL study was a phase II multicenter clinical study in which the response rate (primary endpoint) was assessed by the central review committee and safety was investigated in 10 patients with recurrent or refractory ALK-positive ALCL. It was conducted in three sites, led by Nagoya Medical Center, National Hospital Organization.

As a leading pharmaceutical company in the oncology field in Japan, Chugai will work to provide Alecensa as a new treatment option for ALK-positive ALCL as soon as possible.

About ALK-positive ALCL

ALCL is one of four subtypes of peripheral T-cell lymphoma classified as malignant lymphoma, which is non-Hodgkin’s lymphoma originated in T-cells in lymphocytes. The malignancy is categorized as “intermediate-grade,” in which disease progression is observed on a monthly basis. In Japan, the percentage of ALCL in malignant lymphomas is from 1.5 to 2.0%^{1,2)}, about half of which have been reported as ALK-positive.^{3,4)} Considering that the 5-year survival rate with successful treatment has been

reported to be 60% in patients with ALK-positive ALCL who received chemotherapy in another global study, the percentage of recurrent and refractory cases is estimated to be 40%.³⁾

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- 2 Aoki R, Karube K, Sugita Y, Nomura Y, Shimizu K, Kimura Y, et al. Distribution of malignant lymphoma in Japan: Analysis of 2260 cases. 2001-2006. *Pathol Int.* 2008 Mar; 58(3): 174-82
- 3 Savage KJ, Harris NL, Vose JM, Ullrich F, Jaffe ES, Connors JM, et al. ALK- anaplastic large-cell lymphoma is clinically and immunophenotypically different from both ALK+ ALCL and peripheral Tcell lymphoma, not otherwise specified: report from the International Peripheral T-Cell Lymphoma Project. *Blood.* 2008 Jun 5; 111(12): 5496-504
- 4 Sibon D, Fournier M, Brière J, Lamant L, Haioun C, Coiffier B, et al. Long-Term Outcome of Adults With Systemic Anaplastic Large-Cell Lymphoma Treated Within the Groupe d'Étude des Lymphomes de l'Adulte Trials. *J Clin Oncol.* 2012 Nov 10; 30(32): 3939-46

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