Roche Diagnostics K.K.
Chugai Pharmaceutical Co., Ltd.

Further Improving Access to Therapies for Non-Small Cell Lung Cancer Submitted Application for Partial Changes to Obtain an Additional Indication for “VENTANA OptiView ALK (D5F3)” as a Companion Diagnostic for ALK Inhibitor “Alecensa (alectinib)”

TOKYO, February 1, 2018 -- Roche Diagnostics K.K. (Main Office: Minato-ku, Tokyo. President & CEO: Makoto Ogasawara) announced today that it has filed an application for partial changes for an *in vitro* diagnostic “VENTANA OptiView ALK (D5F3)” to identify ALK-positive non-small cell lung cancer (NSCLC) patients. The company aims to receive regulatory approval of the drug as a companion diagnostic for the treatment with ALK inhibitor “Alecensa” launched by Chugai Pharmaceutical Co., Ltd. (Main Office: Chuo-ku, Tokyo. Chairman & CEO: Osamu Nagayama).

“VENTANA OptiView ALK (D5F3)” is an ALK fusion protein kit launched by Roche Diagnostics. It is currently indicated as an aid to identify NSCLC patients eligible for the treatment with crizotinib and ceritinib. By using an automated immunohistochemistry (IHC) staining instrument from the “VENTANA BENCHMARK” series, it enables efficient and timely results, as an optical microscope can be used for the interpretation of the test, and there is no need for complex procedures.
If an additional indication for the ALK inhibitor "Alecensa" is approved, “VENTANA OptiView ALK (D5F3)” will be the companion diagnostic for all ALK inhibitors currently available in Japan. Roche Diagnostics is confident that the expanded indication of this diagnostic will further contribute to the early diagnosis and early treatment for patients eligible for these treatments.

Alecensa is a highly selective oral ALK inhibitor originated by Chugai. The detection of ALK is mandatory for the treatment with Alecensa, and with the label expansion of “VENTANA OptiView ALK (D5F3)” for Alecensa, it is expected to contribute to the timely and appropriate diagnosis of a positive result for the ALK fusion gene.

Roche Diagnostics and Chugai are members of the Roche Group, a pioneer in personalized healthcare, will continue to dedicate ourselves to provide the right treatment for the right group of patients.

About VENTANA OptiView ALK (D5F3)
VENTANA OptiView ALK (D5F3) is an *in vitro* diagnostic approved in combination with the primary antibody (clone D5F3), a rabbit monoclonal antibody, the highly sensitive detection kit “VENTANA OptiView DAB Universal Kit”, and the “VENTANA OptiView Amplification Kit” that conducts tyramide amplification, making it possible to conduct testing in pathology labs in a more efficient and timely manner. VENTANA OptiView ALK (D5F3) is the only companion diagnostic approved using the IHC method alone to identify patients eligible for treatments with ALK inhibitors.

About Alecensa

It has been reported that approximately five percent of patients with NSCLC express a chromosomal rearrangement which leads to fusion of the ALK gene with another gene[1)]. ALK kinase signalling is constantly active in cells with such fusion genes, resulting in uncontrolled growth of tumour cells and transforming the cells into tumour cells[2, 3)]. Alecensa exerts its anti-tumour effect by selectively inhibiting ALK kinase activity to inhibit tumour cell proliferation and induce cell death[4)].

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 and Turkey 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 as "Alecensa® capsule 150mg" by Chugai under the name.

1) Biomarker committee of The Japan Lung Cancer Society, Guidelines for ALK gene tests in lung cancer patients
2) Soda et al., Nature. 448: 561-566 (2007)
3) Takeuchi et al., Clin Cancer Res. 15: 3143-3149 (2009)
4) Sakamoto et al., Cancer Cell. 19: 679-690 (2011)

About Roche Diagnostics K.K.

Roche Diagnostics K.K. is the Japanese affiliate of the Diagnostics Division of F. Hoffmann-La Roche, one of the world’s leading healthcare companies, based in Basel, Switzerland. As of February 2017, with 727 employees and sales branches in 9 cities across Japan as well as a logistics center, Roche Diagnostics K.K. provides innovative diagnostic solutions for customers ranging from clinical diagnostics to research. Our aim is to continuously provide tests with increased medical value and to improve testing efficiency that ultimately empower healthcare professionals to make better and timely clinical decisions for the people in Japan.

Additional information is available on the Internet at http://www.roche-diagnostics.jp. (Japanese only)

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 2016 of Chugai totalled 491.8 billion yen and the operating income was 80.6 billion yen (IFRS Core basis).
Additional information is available on the internet at https://www.chugai-pharm.co.jp/english.

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