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CHUGAI
Roche Group

Translation

Chugai Initiates Clinical Trials for Multiple In-Licensed Compounds Utilizing the Personalized Healthcare Strategy

Humanized Anti-Met Antibody, MetMAb, and Humanized Anti-IL-13 Antibody, Lebrikizumab

September 2, 2011 (Tokyo) - Chugai Pharmaceutical Co., Ltd. [Head Office: Chuo-ku, Tokyo; President: Osamu Nagayama (hereafter, “Chugai”)] announced today that it has entered into license agreements with F. Hoffmann-La Roche, Ltd [Head Office: Basel, Switzerland / CEO: Severin Schwan (hereafter, “Roche”)] covering humanized anti-Met antibody MetMAb, for non-small cell lung cancer (NSCLC) and humanized anti-interleukin(IL)-13 antibody lebrikizumab for bronchial asthma which are both currently developed by Roche utilizing the Personalized Healthcare (PHC) approach and have also entered phase I clinical studies in the Japanese population. Under the agreement, Chugai obtains rights for the development and marketing of these compounds in Japan, and will make milestone payments to Roche.

PHC is a strategy to combine highly specific diagnostic tests with targeted therapies created based on the understanding of the molecular causes of diseases. This strategy includes the identification of biomarkers* which identify specific medical conditions as well as the patient’s genetic or acquired parameters relevant to the disease. Modern diagnostic tests and targeted medicines enable physicians to provide treatments to those patient sub-groups that have a high likelihood to benefit from the planned therapy and reduce the risk of non-effective therapy or side effects. In addition to the potential for superior efficacy and safety, it is also expected to offer economic advantages.

” MetMAb”

MetMAb is a recombinant humanized, monoclonal, monovalent antibody that targets Met receptor for Hepatocyte Growth Factor (HGF), which is under development by Roche. It has been reported that high level of Met expression was correlated with worse prognosis in NSCLC patients, and also known that EGFR gene mutations or Met amplification could cause acquired resistance for EGFR Tyrosine Kinase Inhibitors (EGFR-TKIs) under the current treatment. MetMab could be administered with erlotinib hydrochloride (Tarceva®), and is expected to become an additional option of the treatment for advanced NSCLC patients expressing high levels of Met.

In Japan, approximately 60,000 patients are estimated to be diagnosed as advanced NSCLC, and that approximately half of them are considered to have high level of Met. The efficacy of MetMAb has been shown in the overseas Phase II study, especially for the patients with high levels of Met.

” Lebrikizumab”
Lebrikizumab is a recombinant humanized, monoclonal antibody that targets IL-13. It is in development by Roche for moderate to severe asthma that is uncontrolled with existing treatment options. It is expected that lebrikizumab will improve the daily symptoms of asthma as well as prevent asthmatic attack.

In Japan, approximately 4 million patients are estimated to be diagnosed as asthma and about 10% of them are considered as patients who are currently not controlled with existing therapy. The efficacy of lebrikizumab was demonstrated by an overseas Phase II study, especially with patients expressing high levels of serum periostin***.

The simultaneous development of companion Met and periostin tests by Roche’s Diagnostics division to detect the respective disease specific biomarkers and identify those patients who are likely to benefit from these compounds is also underway, in line with Roche Group’s PHC approach using biomarkers to develop highly sensitive and reliable diagnostic tools to identify the right medicine for the right patient at the right time.

In addition, Chugai has already initiated the following development programs under the PHC approach:

Name (Code)	Expected Indication	Stage	Origin	Biomarkers
erlotinib (RG1415)	Non-small cell lung cancer (1st line)	Phase II	Roche	EGFR
GA101 (RG7159)	Non Hodgkin’s lymphoma	Phase I	Roche	CD20
pertuzumab (RG1273)	Breast cancer	Phase III (Multinational study)	Roche	HER2
T-DM1 (RG3502)	Breast cancer	Phase III (Multinational study)	Roche	HER2
AF802	Non-small cell lung cancer	Phase I/II	In-house	ALK transfusion gene
GC33	Hepatocellular carcinoma	Phase I (Japan/Overseas)	In-house	Glypican 3
vemurafenib (RG7204/ PLX4032)	Melanoma	Phase I	Roche	BRAF

Chugai is committed to continuing its efforts to meet unmet medical needs by effectively utilizing the research and development resources of Roche to find innovative new drugs.

* Biomarker：a characteristic (biological substance in the body) that is objectively measured and evaluated as an indicator of normal biologic processes, pathogenic processes, or pharmacologic responses to a therapeutic intervention. It serves as basis for the development of diagnostic tests.

**Met: a tyrosine kinase type receptor protein that is activated by its ligand, HGF. Met diagnostics positive is identified as over 50% of cancer cells with moderate to strong stain by immunohistochemical staining.

***Periostin: an extracellular matrix protein that is induced by IL-13, is considered to be related with fibrosis of bronchial pathway cells in patients with asthma.