Results report

1. Title of Research and Development: Development of an innovative diagnostic system against liver fluke infection in Southeast Asian countries

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4. Results of Research and Development:

Cholangiocarcinoma (CCA) is known as intractable cancer with poor prognosis due to complex tumorigenesis and progression variation. In Japan, CCA accounts for about 10% of liver cancer, but in the Mekong region including Thai and Laos, almost 90% of liver cancer is CCA. In Thai, CCA is the most malignant tumor and about 3 million patients die from CCA. CCA progresses slowly with almost no subjective symptoms at the early stage, but the cure rate can be increased if an early clinical intervention is possible. This collaborative research aims to develop and provide innovative diagnostic system for quantitative and low invasive evaluation of the progress or risk of CCA associated with liver fluke infection using our advanced technologies for glycoscience in collaboration with the Thai and Lao researchers.

This project was started in June 2015. The main objectives of the first fiscal year were the construction of the basis for international communications and collaborative research as well as the mutual agreement on the task and establishment of the project plan. The preliminary meeting was held on July 22 in Kumamoto, Japan to discuss the current situation and solution for establishment and implementation of the assay hub with participation of 3 members from the Japanese team and 2 from the Thai team. In November, all collaborators (5 from Japan, 3 from Thai, and 3 from Lao) gathered in Tsukuba for the kick-off meeting and agreed on the mission and goal of the project. Moreover, details of the Thai and Japanese marker candidates were presented, and the initial comparative study was planned to be conducted by the end of the fiscal year. Thereafter, mail-based communication was kept among the teams and the first annual meeting was held in Khon Kaen, Thailand and Vientiane, Laos in February (all but one participants of the kick-off meeting joined). The members visited the labs and medical facility of KKU and UOH, and discussed the project plan for the coming year. The collaborative research contract and other paper work are under preparation so that they can be finalized early in the next fiscal year.

As the experimental work, efficiency of two markers established by KKU was determined in blind ELISA assay by a KKU researcher who is currently belonging to the Kumamoto Univ using ethically approved CCA serum samples which were collected from Japanese patients and maintained at AIST. The manual assay technique of the marker established in AIST was transferred to this researcher, and he returned to Kumamoto Univ and assayed another serum library (ethically approved Thai samples). Accordingly the three marker candidates were measured and statistically analyzed in a total of 355 samples. In the result, the Japanese marker showed favorable results in detection of CCA with similar tendency in both Japanese and Thai samples. The two KKU markers showed good results in the Thai samples and have characteristics different from those of the Japanese marker, which would become an advantage in combinational use. However, the KKU markers could not distinguish CCA from benign diseases in the Japanese samples. Since the number of benign samples in the Thai cohort was small, about 150 of ethically approved samples were additionally assayed. Statistical analysis is being conducted, and the results will be reflected in the study plan of the coming fiscal year.