Information

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(Code: 4583, Tokyo Stock Exchange Growth)

Announcement of Paper Publication on the First Part of the CBA-1205 Phase I Clinical Study

The research results of the first part of the CBA-1205 Phase I clinical study were published in an international academic journal, *Cancer Science*.

This paper presents the results of the first part of the CBA-1205 Phase I clinical study conducted on patients with solid tumors, which our company is currently developing. In this part, 22 Japanese patients who had no standard therapy available or were refractory or intolerant to standard therapy participated. After the safety evaluation of a single administration of CBA-1205, no dose-limiting toxicity or significant side effects were observed in all planned doses, and the evaluation confirmed its high safety. In addition, the stable condition of the disease continued for more than 6 months in 6 out of 22 patients. In particular, a malignant melanoma (a type of high-risk skin cancer) patient remained in stable condition for more than 36 months (at the time of data collection) with about 20% tumor shrinkage, and the administration of CBA-1205 is still ongoing. Furthermore, DLK1 levels in the blood were higher in patients with stable condition than in those with progress disease. Although further study is needed as the evaluation was based on a small number of patients, we discuss the possibility that DLK1 levels in the blood could serve as a predictive biomarker of CBA-1205 efficacy.

- Publication

  Title : A Phase I, first-in-human study of CBA-1205, an anti-DLK1 monoclonal antibody, in patients with advanced solid tumors

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<CBA-1205>

CBA-1205 is a human IgG1 monoclonal antibody that selectively binds to DLK1, and ADDC activity has been enhanced by glycosylation engineering technology called Glymax® (ProBioGen, Berline). We are currently conducting Phase I study of CBA-1205 independently in Japan. The study's primary endpoint is to evaluate the safety and tolerability in cancer patients. The subjects are patients with solid tumors in the first part, while patients with hepatocellular carcinoma are in the second part of the study. As the patient enrollment of the first part has completed and it confirmed the high safety of CBA-1205, we are conducting the patient enrollment of the second part of the study with hepatocellular carcinoma patients. So far, the study has confirmed high safety in hepatocellular carcinoma patients as seen in the first part of the study. A secondary efficacy evaluation confirmed more than 30% shrinkage (partial response) of a tumor in one patient with hepatocellular carcinoma. We are conducting the study by tightening the eligibility criteria for patients with hepatocellular carcinoma, aiming to include additional study cases showing tumor shrinkage with CBA-1205. Notably, in a patient with malignant melanoma enrolled in the first part of the study, the stable condition of the disease has lasted more than 42 months. Considering these factors and interim results we have started a small cohort of melanoma in the second part of Phase 1 to assess its safety and potential in melanoma patients.

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