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Representative: Shigeru Kobayashi, President & CEO
(Code: 4583, Tokyo Stock Exchange Growth)

Announcement of Paper Publication on CBA-1205 Non-Clinical Data

The research results were published in an international academic journal International Journal of Molecular Sciences. The paper discusses the findings on the non-clinical data for CBA-1205, a therapeutic antibody for cancer treatment currently in clinical trials at our company.

In this study, CBA-1205, which selectively binds to delta-like 1 homolog (DLK1), destroyed cells expressed DLK1 through Antibody-Dependent Cellular Cytotoxicity (ADCC) activity. CBA-1205 also inhibited tumor growth on mouse-model transplanted with human liver cancer cells expressing DLK1. Furthermore, by combining with Lenvatinib, an standard of care of hepatocellular carcinoma, CBA-1205 inhibited tumor growth more effectively than single-dose administration in the same animal model. This combining effect of Lenvatinib and CBA-1205 lasted long during the observation period after the administration. In the toxicology study using cynomolgus monkeys, it showed no serious toxicological changes caused by the administration of CBA-1205. As a result of these findings, the paper discusses the potential of CBA-1205 as one of the treatment options for patients with hepatocellular carcinoma.

➤ Publication

Title : A Novel Glycoengineered Humanized Antibody Targeting DLK1 Exhibits Potent Anti-Tumor Activity in DLK1-Expressing Liver Cancer Cell Xenograft Models
Authors : Koji Nakamura, Kota Takahashi, Izumi Sakaguchi, Takumi Satoh, Zhang Lingyi, Hiroyuki Yanai, Yukihito Tsukumo
Journal : International Journal of Molecular Sciences
<https://www.mdpi.com/1422-0067/25/24/13627>

<CBA-1205>

CBA-1205 is a human IgG1 monoclonal antibody that selectively binds to DLK1, and ADCC 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 (a type of high-risk skin cancer) enrolled in the first part of the study, the stable condition of the disease has lasted more than 39 months, and CBA-1205 dosing is still ongoing. Considering these factors and interim results we have decided to open 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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