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Move to the second half part of Phase 1 clinical trial of first-in-class CBA-1205

This is to announce that we have successfully completed patient enrollment in the first part of phase I study of CBA-1205. CBA-1205 is the first in-class antibody which Chiome has been developing for cancer treatment. As a result of the safety evaluation, which is the primary objective of this part, Principal investigators and Chiome agreed with moving to the second part of phase I study to evaluate the safety and initial efficacy in patients with hepatocellular carcinoma.

In the first part of the phase I study, which started in July 2020, the safety, tolerability, and pharmacokinetics of CBA-1205 were evaluated in patients with various solid tumors. This part is called “dose escalation part” where the patients are assigned to one of the several dose groups that are administered each dose in the order of the lowest to the highest dose to determine the highest dose that can be given safely without causing unacceptable side effects for the second part of the study.

As the safety of this antibody has been proven to be high in the course of the first part, the original protocol was amended to add the higher dose groups to be administered.

In December, enrollment in the first part of the phase I study of CBA-1205 has completed at The National Cancer Center Hospital and East Hospital. Principal investigators and Chiome concluded that this antibody was safe and well tolerated and that it was possible to conduct the second part of the study.

In the second part, only patients with hepatocellular carcinoma will be enrolled and given CBA-1205 to evaluate safety and initial efficacy.

There is no impact on the financial performance in the fiscal period ending December 31, 2021.

＜About CBA-1205＞

CBA-1205 is an afucosylated humanized antibody targeting cell surface antigen “DLK-1 (Delta-like 1homolog)” which expresses on hepatocellular carcinoma and other solid cancers. CBA-1205 exhibits potent and specific anti-tumor activity in various DLK-1 expressing cancer models. DLK-1 is known to control the proliferation and differentiation of stem cells, progenitor cells, and other immature cells.

CBA-1205 is expected to offer a new therapeutic option for the treatment of DLK-1 expressing cancer such as hepatocellular carcinoma.