

Feb. 16, 2022

Company: Chiome Bioscience Inc.

Representative: Shigeru Kobayashi, President & CEO

(Code: 4583, Tokyo Stock Exchange Mothers)

Submission of the application for a Phase I study of CBA-1535

Chiome Bioscience Inc., announced today that it has submitted an initial application for a Phase I study on CBA-1535 to the Pharmaceuticals and Medical Devices Agency (PMDA) on February 16, 2022.

CBA-1535 is a trispecific antibody binding to 5T4 which highly expresses on solid tumor cells and CD3 on the surface of immune T cells. It forms a synapse between the both cells and activates patients' intrinsic T cells that leads to killing the cancer cells. (This mechanism is called "T cell engager" .)

CBA-1535 is produced by the trispecific antibody generation technology called as Tribody™.

This is the first-in human study of multi-specific antibody in Tribody™ and consists of 2 parts. The first part is a dose escalation to assess the safety and initial pharmacokinetics as a single agent. The second part is an expansion part where safety and preliminary efficacy are evaluated in combination with cancer immunotherapy agent.

In addition to the safety and efficacy, obtaining proof of concept as a T cell engager is a major objective. Once it is proved Tribody™ technology could be applicable to multiple types of tumor antigen.

After submission of the application all the common regulatory procedure will be proceeded. We expect the first dosing in early 2H.

There is no impact on the financial performance in the fiscal period ending December 31, 2022.

<About CBA-1535>

CBA-1535 is cancer therapeutic antibody with three antigen binding sites; two of them bind to 5T4 protein that expresses on various solid tumor, and the third one bind to CD3 protein on the surface of immune T cells. CBA-1535 is anticipated to exhibit potent cytotoxicity by inducing T cell proliferation and activation. 5T4 expresses on malignant mesothelioma, small cell lung cancer, and non-small cell lung cancer, and other solid tumors. This is in a tract of our mission of shining light on unmet medical needs through development of therapeutic antibody.

【Inquiries】

Chiome Bioscience Inc. Investor Relations

E-mail : ir@chiome.co.jp