GIST faculty startup company JD Bioscience Co., Ltd. receives US FDA approval for Phase 2a Clinical Trial for new fatty hepatitis drug 'GM-60106'

- Department of Chemistry Professor Jin Hee Ahn, Startup Company, Global Clinical Phase 2 full-scale entry into full-scale Phase 2 for treatment of fatty liver disease... New drug candidate 'GM-60106' simultaneously suppresses fatty liver accumulation and liver fibrosis

- Phase 1 Clinical Trial completed with support from National New Drug Development Project... Expected to accelerate rapid patient recruitment and global market entry along with promoting strategic partnerships for successful Phase 2 Clinical Trials

▲ Jin Hee Ahn, CEO of JD Bioscience, a faculty-run company (Professor of Chemistry, GIST)

The Gwangju Institute of Science and Technology (GIST, President Kichul Lim) announced that the new drug candidate ‘GM-60106’ developed by JD Bioscience, a faculty startup (CEO Jin Hee Ahn, Professor of Chemistry at GIST), received approval for a global phase 2a clinical trial plan (IND) from the U.S. Food and Drug Administration (FDA).

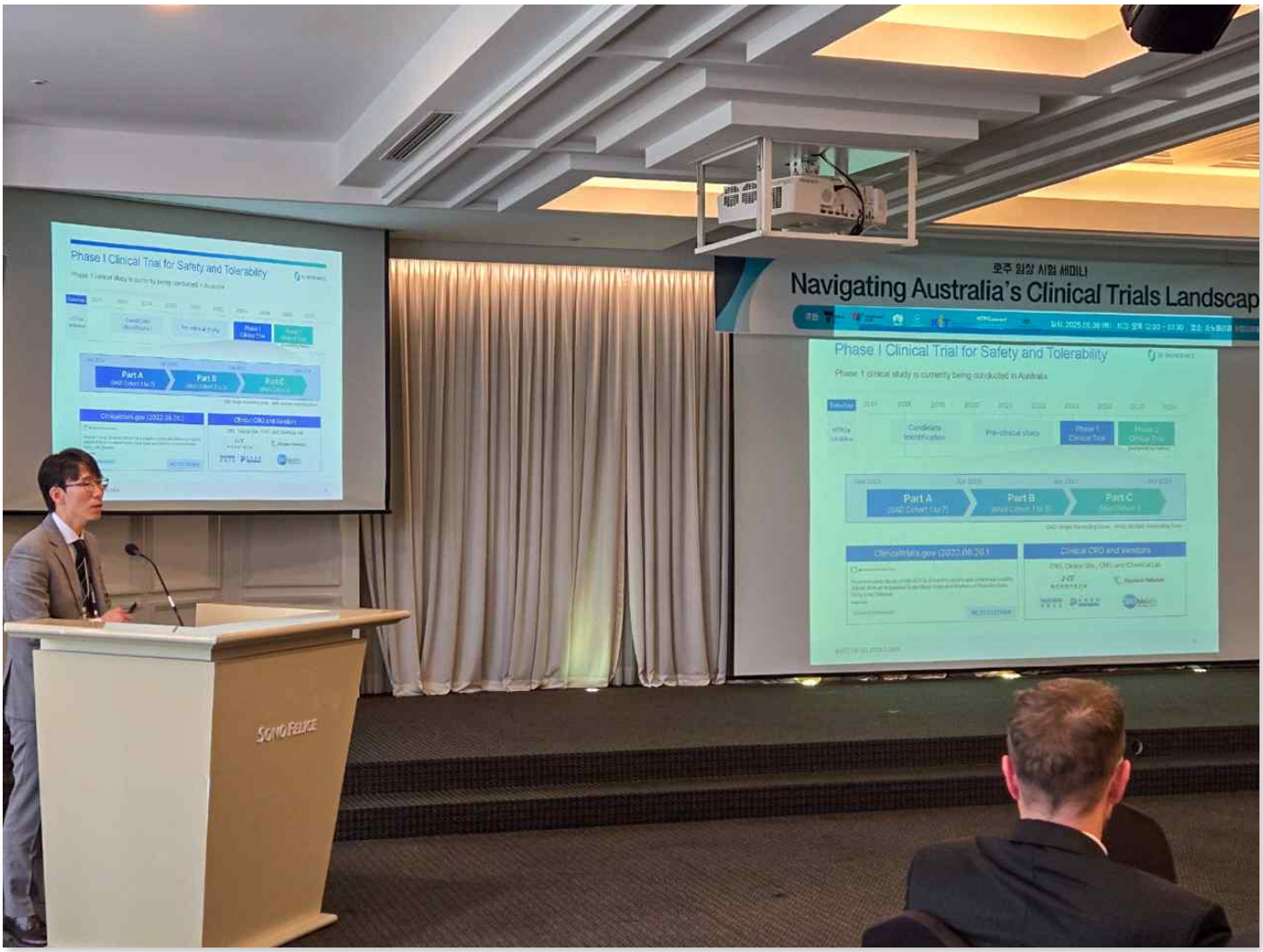
‘GM-60106’ is a small molecule compound-based new drug candidate currently under development for the treatment of metabolic dysfunction-associated steatohepatitis (MASH).

This substance was developed through technology transfer from GIST in 2018, and has the characteristic of simultaneously inhibiting fatty liver accumulation and liver fibrosis through a new mechanism of action (first-in-class) that inhibits the HTR2A receptor*.

* HTR2A receptor: A type of serotonin receptor distributed in the brain and nervous system, it binds to serotonin and regulates various brain functions such as emotional control, cognitive function, memory, and sleep. This receptor is closely related to mental illnesses such as depression and schizophrenia, and is an important target for drug treatment, and is also involved in the mechanism of action of some hallucinogens.

JD Bioscience Co., Ltd. has been preparing for clinical trials in the United States in cooperation with IQVIA, a global clinical trial contract organization (CRO), starting with a pre-IND meeting with the US FDA in November 2024. Afterwards, it submitted an IND to the FDA on March 31 of this year and received approval for a phase 2a clinical trial on April 29.

With this approval, JD Bioscience Co., Ltd. announced that it plans to begin recruiting patients as soon as possible, either alone or in collaboration with a technology transfer target company, and to quickly administer the first patient.



▲ JD Bioscience officials are announcing the clinical trial at the Australian clinical trial seminar held at the Sono Felice Convention on May 8.

This clinical trial is a proof of concept (PoC) study conducted on 90 MASH patients, and will evaluate the safety, efficacy, biological activity, and pharmacodynamic characteristics of 'GM-60106.' The trial will be conducted in a randomized, double-blind, placebo-controlled manner at several hospitals in the United States for 12 weeks.

In particular, this study set the MRI-PDFF (magnetic resonance imaging-based proton density fat fraction) that measures changes in the fat content in the liver as the primary endpoint*, and plans to evaluate inflammation, liver fibrosis, and insulin resistance as secondary or exploratory endpoints*.

* In a clinical trial, an endpoint is a pre-determined standard for evaluating the efficacy or safety of a drug. The primary endpoint is the most important indicator for determining the core objective of the clinical trial, and the secondary endpoint is an auxiliary indicator for evaluating additional effects or side effects. On the other hand, an exploratory endpoint is an experimental indicator that is not a clearly proven standard, but is set to find out other possibilities or additional effects of a new drug, and is usually used to determine the direction of future research.

CEO Jin Hee Ahn said, "With this approval for phase 2a clinical trials, we have become even more confident in the innovation of GM-60106 and its potential as a treatment," and added, "We are actively pursuing collaboration with strategic partners to successfully conduct phase 2 clinical trials."

He added, "We are seeking various forms of partnerships, such as joint development and technology transfer, with domestic and foreign pharmaceutical companies, and are aiming for rapid entry into the global market."

Meanwhile, the phase 1 clinical trial of the new drug candidate 'GM-60106' was conducted with the support of the 'National New Drug Development Project' hosted by the National Drug Development Fund (Director Young-min Park). This project is a government-led project in which the government financially supports the entire process of new drug development, from non-clinical trials to clinical trials, licensing, and technology transfer.

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