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Nihon Medi-Physics Co., Ltd.

FDA Accepts NMP's Clinical Trial Application for Development of NMK89 as Imaging Agent for Cancer Diagnosis

- Clinical Study Set to Begin, Focusing on Diagnostic Use of Theranostics -

Nihon Medi-Physics Co., Ltd. (NMP), a leading radiopharmaceutical company in Japan, is pleased to announce that the U.S. Food and Drug Administration (FDA) has recently accepted NMP's Investigational New Drug (IND) application to initiate a first-in-human phase I clinical study of "NMK89 (development code)," which is an imaging agent currently developed for cancer diagnostic use in cancer theranostics (a fusion of therapeutics and diagnostics) (*1). The clinical study can now be started.

NMK89 is an RI (*2)-labeled humanized anti-MUC5AC (*3) antibody to which zirconium-89, a diagnostic radionuclide, is labeled and has been investigated in non-clinical studies conducted by NMP and Sumitomo Pharma Co., Ltd. as an imaging agent for the diagnosis of MUC5AC-expressing cancer. It has been reported that MUC5AC is highly expressed in pancreatic cancer, liver cancer, colon cancer, gastric cancer, and lung cancer, among others. Non-clinical studies have confirmed that NMK89 accumulates in tumors transplanted with cell lines expressing MUC5AC.

NMP is developing NMK89 in one of the research projects (*4) adopted by the Japan Agency for Medical Research and Development (AMED) to enable early commercialization of theranostics for use in nuclear medicine.

NMP is conducting the phase I study of NMK89 in the U.S. NMP will promptly begin clinical studies of therapeutic drugs by leveraging the data on NMK89, obtained from the phase I study, to swiftly materialize it as long-awaited theranostics.

Notes:

(*1) It is a therapeutic concept in which RI-imaging diagnostics is used in advance to determine whether the drug reaches the target protein in the patient and to provide treatment with the radionuclide modified for therapeutic use. This enables therapies that are more closely aligned with a diagnosis and is expected to contribute to personalized medicine and the effective utilization of medical costs.

(*2) Radioisotopes - Radiation they emit is used for cancer treatment and diagnosis.

(*3) Mucin subtype 5AC - A type of mucin which is the main component of mucus secreted by animal epithelial cells. It is generally expressed in normal tissues of the stomach and trachea but is also reported to be highly expressed in pancreatic cancer and several other cancers.

(*4) The research project known as "Development of Antibody Labeling Therapies (with Alpha-Particle) and Companion Diagnostics, in Parallel with Maintenance of Drug Research Facilities to Embody the Concept of Theranostics" was adopted by AMED's "Cyclic Innovation for Clinical Empowerment (**C*i*CLE**)" - FY2017 (2nd Conference).

About Nihon Medi-Physics Co., Ltd.

Nihon Medi-Physics is engaging in ensuring stable supply and research and development of new products as a leading manufacturer of radiopharmaceuticals in Japan. Based on the technological proficiency and trust built over the years, the company is also working on research and development of "theranostics (a combination of therapeutics and diagnostics)," which is a novel medical technology to provide optimal medical service to each patient, as well as on the dissemination of nuclear medicine in Asian countries by licensing its products. The company will continue contributing to society by creating values as a life science company.

Official website: https://www.nmp.co.jp/eng/index.html

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