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Eisai Co., Ltd.

INDUSTRY-ACADEMIA-GOVERNMENT JOINT DEVELOPMENT AGREEMENT AIMING FOR DRUG DISCOVERY FOR SYSTEMIC LUPUS ERYTHEMATOSUS BY PRACTICAL APPLICATION OF TOLL-LIKE RECEPTOR RESEARCH CONCLUDED

RESEARCH ACTIVITIES COMMENCE

Eisai Co., Ltd. (Headquarters: Tokyo, CEO: Haruo Naito, "Eisai") announced today that it has entered into an industry-academia-government joint research agreement with four universities in Japan concerning the "Industrialization of Japan-originated Toll-like receptor research by Academia-Industry collaborating All-Japan system: Creation of new drug for SLE treatment", which is a research project with Eisai as the representative research organization. This joint research project was selected by the Japan Agency for Medical Research and Development (AMED) for its Cyclic Innovation for Clinical Empowerment (CiCLE) grant program. In this project, Eisai aims at creating a Japan-originated therapeutic drug for systemic lupus erythematosus (SLE) through industry-academia-government collaboration, using its in-house discovered new oral Toll-Like Receptor (TLR) 7/8 inhibitor E6742.

SLE is a designated intractable autoimmune disease that causes various organ disorders involving the disorders of the skin and the musculoskeletal system. The estimated number of patients with SLE in Japan is 60,000 to 100,000. In particular, the onset of SLE appears more commonly in females in their 20s to 40s. As such, SLE is a disease with extremely high unmet medical needs. The current treatment mainstays are corticosteroids, hydroxychloroquine, and an immunosuppressant, but the development of new effective therapeutic agents with fewer side effects is desired.
According to the latest research findings, it has been reported that TLR7/8, a member of the TLRs-family of receptors, is associated with the pathogenesis of SLE, suggesting the possibility of controlling SLE by a TLR7/8-specific inhibitor. E6742 has selective and potent inhibitory activity against TLR7/8, and is expected to potentially become a new therapeutic agent for SLE.

In this project, Eisai will conduct the clinical development of E6742. In addition, the top-class research institutes for TLR and SLE research in Japan (University of Occupational and Environmental Health, Japan; Osaka University; Hokkaido University; Tohoku University) and Eisai's research subsidiary KAN Research Institute will carry out an academic-driven clinical observational research in order to clarify the pathogenesis of SLE.

By creating new innovation based on industry-academia-government collaboration and fulfilling unmet medical needs, Eisai will contribute to increasing the benefits of patients and their families.

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[Notes to editors]

1. About C*i*CLE

AMED's C*i*CLE is a grant program to promote the establishment of infrastructure (including human resources) to respond to medical needs and the creation of an environment for open innovation and venture development based on industry-academia-government collaboration.

2. About TLR and E6742

TLRs are receptors of the innate immune system, and recognize the specific molecular structure of pathogens. It is considered that TLR initiated activation of the innate immune system plays a critical role in eliminating pathogens, causing an inflammatory reaction or an antiviral response. TLRs constitute a family of various receptors. According to the latest research findings, it has been reported that TLR7/8, a member of the TLRs-family of receptors, is associated with the pathogenesis of SLE, suggesting the possibility of controlling SLE disease by a TLR7/8-specific inhibitor. E6742 is a highly active and selective TLR7/8 inhibitor created by Eisai's former Andover Research Laboratories in the United States. In non-clinical studies, E6742 has been shown to suppress TLR7/8 stimulation induced cytokine production specifically and potently, and in addition, in a mouse model with SLE-like pathological conditions, it has been confirmed that E6742 is effective in improving the pathology. Furthermore, a Phase I single dose clinical trial of E6742 has been completed in the United States.

3. Systemic Lupus Erythematosus (SLE)

Systemic Lupus Erythematosus (SLE) is a systemic autoimmune disease induced by antibodies that causes various organ disorders involving disorders of the skin and the musculoskeletal system. About 90% of patients with SLE are female, especially among 20-40 years old, and the estimated number of patients is 60,000 to 100,000 in Japan. The cause of SLE is unknown, and it is designated as an intractable autoimmune disease in Japan (Designation 49)[1]. In Japan, the global standard drug for SLE, hydroxychloroquine, was approved in 2015 and the biologic berimumab was approved as a treatment for SLE in 2017, respectively. However, SLE is a disease with huge unmet medical needs, with great expectations for the establishment of new treatment options.

4. Activity of AMED's C*i*CLE in Eisai

As a key initiative for industry-academia-government collaboration in which Eisai is participating, a project aiming to identify and verify novel drug discovery target candidates linked to the development of next-generation treatments and preventative medicines for dementia at the Eisai-Keio Innovation Lab for Dementia (EKID) (Location: Keio University Shinanomachi campus) has also been selected by AMED for the C*i*CLE program. In addition, a research project represented by KAN on nucleic acid drug discovery research using novel nucleic acid synthesis and delivery technologies, and an initiative originated in Japan to develop biologics and new biomarkers for Crohn's disease represented by Eisai's gastrointestinal disease business subsidiary EA Pharma Co., Ltd. have been respectively selected by AMED for C*i*CLE.

1. Japan Intractable Diseases Information Center - systemic lupus erythematosus (SLE) (Designation 49): https://www.nanbyou.or.jp/entry/53 (Available in Japanese only)