

September 21, 2023 Nobelpharma Co., Ltd.

Investigator-Initiated Phase II Trial Completed: Sirolimus Gel for Vascular Abnormality-associated Skin Lesions

Nobelpharma Co., Ltd. (Headquarters: Chuo-ku, Tokyo, Managing Director & CEO: Jin Shiomura) announced that the company was notified by Dr. Masatoshi Jinnin, Professor of Dermatology at Wakayama Medical University Hospital, that the last patient had been examined (last patient out; LPO) since the first patient registered in December 2021 in the investigator-initiated phase II trial "A randomized, multicenter, double-blind, placebo-controlled clinical trial of sirolimus gel in cutaneous manifestation of patients with vascular (WMU-NPC-1)" (JRCT2051210126) for which the company collaborated as the investigational drug provider. Hereafter, the preliminary report is anticipated around January/February next year after the code break within this year.

This trial was conducted as a project of Japan Agency for Medical Research and Development (AMED), "Project Promoting Clinical Trials for Development of New Drugs," in 2021 (JP23lk0201145) at six medical institutions nationwide to exploratively evaluate the efficacy and safety of sirolimus gel in patients with vascular abnormality-associated skin lesions.

From this point forward, the company will take over the results of the said trial and advance the development of sirolimus gel to obtain an approval for the additional indication, making it a new treatment option for patients with vascular abnormality-associated skin lesions.

We are determined to continue contributing to society by providing critical but neglected pharmaceuticals and medical devices.



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