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Meiji Seika Pharma Co., Ltd.

June 27, 2023

New Drug Application of ME3208 (belumosudil mesilate), a selective ROCK2 inhibitor, submitted in Japan for the treatment of cGVHD

Meiji Seika Pharma Co., Ltd. (Headquarters: Tokyo, Japan, President and Representative Director: Daikichiro Kobayashi) today announced that a New Drug Application (NDA) for ME3208 (JAN: belumosudil mesilate, INN: belumosudil), a selective rho-associated, coiled-coil containing protein kinase 2 (ROCK2) inhibitor, has been submitted to Japan's Ministry of Health, Labour and Welfare for the treatment of chronic graft-versus-host disease (cGVHD) in case of insufficient response to steroid therapy. ME3208 has been granted orphan drug designation by Ministry of Health Labor and Welfare in Japan for the treatment of cGVHD.

The NDA submission is based on results from a phase III clinical study in Japan (jRCT2011210041). The study was designed as an open-label, uncontrolled, single-arm trial to evaluate efficacy and safety of ME3208 in Japanese patients with cGVHD. ME3208 met the primary endpoint, best overall response rate (best ORR), which was defined as the percentage of patients who achieved complete response (CR) or partial response (PR). Details of the study will be presented by Meiji Seika Pharma.

Chronic GVHD is a complication that develops after hematopoietic stem cell transplantation performed as a treatment for hematologic cancers, including leukemia, and is a disease with limited treatment options. ME3208 is the first and currently the only selective inhibitor of Rho-associated coiled-coil protein kinase 2 (ROCK2), a kinase involved in immune cell differentiation and tissue fibrosis, that exerts immunomodulatory and anti-fibrotic effects, and is expected to be effective in cGVHD. The U.S. Food and Drug Administration (FDA) has granted Breakthrough Therapy Designation and Orphan Drug Designation, as well as the Priority Review status, to belumosudil for the treatment of cGVHD. Belumosudil is commercially available as Rezurock® to prescribed patients in the US from August 2021 and in Canada and Great Britain from March 2023.

In Japan and 12 Asian countries, Romeck Pharma, LLC, the joint venture between Meiji and Kadmon Corporation, LLC (Headquarters: New York City, U.S.A.), a Sanofi company, has the exclusive right to develop and commercialize ME3208. In South Korea, an NDA has been submitted in March 2023.

Meiji Seika Pharma seeks to address unmet medical needs in the field of hematology by developing ME3208 for the treatment of cGVHD in Japan.