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Meiji Seika Pharma Co., Ltd.

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ME3208 (belumosudil mesilate), a selective ROCK2 inhibitor, received orphan drug designation in Japan for the treatment of cGVHD

Meiji Seika Pharma Co., Ltd. (Headquarters: Tokyo, Japan, President and Representative Director: Daikichiro Kobayashi, “Meiji”) today announced ME3208 (JAN: belumosudil mesilate), a selective rho-associated, coiled-coil containing protein kinase 2 (ROCK2) inhibitor, has been granted orphan drug designation by Ministry of Health Labor and Welfare in Japan for the treatment of chronic graft-versus-host disease (cGVHD).

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 exerts immunomodulatory and anti-fibrotic effects by selectively inhibiting ROCK2, a kinase involved in immune cell differentiation and tissue fibrosis, 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 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 United Kingdom 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 Japan, Phase III clinical trials by Meiji in patient with cGVHD is ongoing. In South Korea, an NDA has been submitted in March 2023.

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