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Meiji Seika Pharma Co., Ltd.

March 26, 2024

Meiji Seika Pharma receives Manufacturing and Marketing Approval of REZUROCK® (belumosudil mesilate), a Selective ROCK2 Inhibitor, from MHLW in Japan for the Treatment of cGVHD

Meiji Seika Pharma Co., Ltd. (Headquarters: Tokyo, Japan, President and Representative Director: Daikichiro Kobayashi) today announced that it has received approval for the manufacturing and marketing of "REZUROCK® Tablets" (JAN: belumosudil mesilate, INN: belumosudil), a selective rho-associated, coiled-coil containing protein kinase 2 (ROCK2) inhibitor, from the Ministry of Health, Labour and Welfare (MHLW) in Japan, for the treatment of chronic graft-versus-host disease (cGVHD) in patients who have insufficient response to steroid therapy.

REZUROCK® is the first and currently the only selective inhibitor of ROCK2, a kinase involved in immune cell differentiation and tissue fibrosis. It exerts its effect by decreasing the inflammation and fibrosis in various organs which are the two key features of cGVHD. In the phase III clinical study in Japan (jRCT2011210041), the primary endpoint was met, best overall response rate (best ORR), defined as the percentage of patients who achieved complete response (CR) or partial response (PR), was 85.7%. Details of the study results was presented at the 46th JSTCT* Annual Meeting held in March 2024 (Press release on March 22).

Chronic GVHD is a complication that develops after allogeneic hematopoietic stem cell transplantation performed as a treatment for various malignant (e.g., leukemia) and non-malignant disease (e.g., severe aplastic anemia) which involves multiple organs, and is a disease with limited treatment options. The U.S. Food and Drug Administration (FDA) has granted Breakthrough Therapy Designation and Orphan Drug Designation to REZUROCK® as treatment of adult and pediatric patients 12 years and older with chronic graft-versus-host disease (chronic GVHD) after failure of at least two prior lines of systemic therapy. The Japan's MHLW has also granted orphan drug designation in May 2023 for the treatment of cGVHD.

REZUROCK® is commercially available to prescribed patients in several countries, including 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 Seika Pharma and Kadmon Corporation LLC (Headquarters: New York City, U.S.A.), a Sanofi company, has the exclusive right to develop and commercialize REZUROCK®.

Meiji Seika Pharma will address unmet medical needs in the field of hematology by distributing REZUROCK® for the treatment of cGVHD in Japan.

*: The Japanese Society for Hematopoietic Stem Cell Transplantation