ENGLISH TRANSLATION

January 8, 2021

Meiji Seika Pharma Initiates Phase 1 Trial of ME3208 in Japan for cGVHD

Meiji Seika Pharma Co., Ltd. (Headquarters: Tokyo, Japan, President and Representative Director: Daikichiro Kobayashi, "Meiji") today announced the initiation of a Phase 1 clinical trial of ME3208 (USAN: belumosudil) in Japan for the treatment of chronic graft-versus-host disease (cGVHD). ME3208 selectively inhibits Rho-associated coiled-coil kinase 2 (ROCK2), a protein kinase that modulates immune and fibrotic processes.

Romeck Pharma, LLC, the joint venture between Kadmon Corporation, LLC (Headquarters: New York, New York, United States, President and CEO: Harlan W. Waksal, M.D., "Kadmon") and Meiji, has the exclusive right to develop and commercialize ME3208 in Japan and certain other Asian countries. Meiji is responsible for development of ME3208 in Japan.

Kadmon is developing ME3208 (belumosudil) for the treatment of cGVHD in the United States. The U.S. Food and Drug Administration (FDA) has granted Breakthrough Therapy Designation and Orphan Drug Designation to belumosudil for the treatment of cGVHD. In November 2020, FDA accepted and granted Priority Review for the New Drug Application (NDA) for belumosudil for the treatment of patients with cGVHD.

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

About ME3208 (Belumosudil)

ME3208 (belumosudil) is a selective oral inhibitor of ROCK2, a signaling pathway that modulates inflammatory response and pro-fibrotic processes. In November 2020, the FDA accepted the NDA for belumosudil for the treatment of patients with cGVHD. The FDA granted Priority Review for the NDA for belumosudil and assigned a Prescription Drug User Fee Act (PDUFA) target action date of May 30, 2021. The NDA is being reviewed under the FDA's Real-Time Oncology Review (RTOR) and Project Orbis pilot programs. The FDA has granted Breakthrough Therapy Designation to belumosudil for the treatment of patients with cGVHD after failure of two or more lines of systemic therapy as well as Orphan Drug Designation to belumosudil for the treatment of cGVHD.

About cGVHD

cGVHD is a common and often fatal complication following hematopoietic stem cell transplantation. In cGVHD, transplanted immune cells (graft) attack the patient's cells (host), leading to inflammation and fibrosis in multiple tissues, including skin, mouth, eye, joints, liver, lung, esophagus and gastrointestinal tract.

About Kadmon

Kadmon Corporation, LLC is a wholly owned subsidiary of Kadmon Holdings, Inc. (Nasdaq: KDMN), a biopharmaceutical company developing innovative products for significant unmet medical needs. Kadmon's product pipeline is focused on inflammatory and fibrotic diseases as well as immuno-oncology (www.kadmon.com).