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Meiji Seika Pharma Co., Ltd.

November 1, 2021

Meiji Seika Pharma initiates Phase 3 Trial of ME3208 in cGVHD in Japan

Meiji Seika Pharma Co., Ltd. (Headquarters: Tokyo, Japan, President and Representative Director: Daikichiro Kobayashi, “Meiji”) today announced the initiation of a Phase 3 clinical trial of ME3208 (INN: 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.

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 July 2021, FDA approved belumosudil for the treatment of patients with cGVHD after failure of at least two prior lines of systemic therapy. From August 2021, belumosudil is commercially available for shipment to prescribed patients in the US.

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

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).