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Meiji Seika Pharma Co., Ltd.

May 22, 2024

Meiji Seika Pharma Launches *REZUROCK® Tablets* (belumosudil mesilate), a Selective ROCK2 Inhibitor, 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 launched in Japan, on behalf of Romeck Pharma LLC, "*REZUROCK® Tablets*" (JAN: belumosudil mesilate, INN: belumosudil), a selective rho-associated, coiled-coil containing protein kinase 2 (ROCK2) inhibitor, for the treatment of chronic graft-versus-host disease (cGVHD) in patients who have insufficient response to steroid therapy. It received manufacturing and marketing approval on March 26, 2024 and is currently listed on the National Health Insurance (NHI) Drug Price List in Japan.

Chronic graft-versus-host disease (cGVHD) presents a multifaceted challenge, with unmet needs spanning physical, emotional, and social realms. Physically, patients endure symptoms ranging from debilitating fatigue and chronic pain to organ dysfunction, which often persist long after the transplant. These enduring and deleterious features of cGVHD are driven by two major physiological responses, inflammation and fibrosis. cGVHD is the leading cause of non-relapse mortality and morbidity in patients that have undergone an allogeneic stems cell transplant, with organ failure and infection as the leading causes [1,2]. In Japan, nearly 4,000 patients every year undergo an allogenic stem cell transplant [3].

REZUROCK is the first approved and only selective therapy inhibiting ROCK2, a signalling pathway playing a major role in the body's inflammatory and fibrotic responses. On March 22, 2024 at the 46th JSTCT Annual Meeting of Japanese Society for Transplantation and Cellular Therapy held in Tokyo, Meiji Seika Pharma Co., Ltd. announced positive findings from the phase III clinical trial of belumosudil (JAN: belumosudil mesilate, Development code: ME3208) in patients with steroid-dependent /resistant cGVHD conducted in Japan (jRCT2011210041) [4]. It is commercially available to prescribed patients with cGVHD in several countries, including the US, Canada and Great Britain. 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® in Japan and twelve Asian countries.

Meiji Seika Pharma will address unmet medical needs in the field of hematology by distributing and promoting REZUROCK® on behalf of Romeck Pharma LLC for the treatment of cGVHD in Japan.

References

1. *Salhotra, A., Eiznhamer D., Hennegan, K. et al (2020). Presentation and management of chronic graft-versus-host disease in real-world clinical practice: A medical chart audit. EHA Virtual Congress, Abstract EP1436*
2. *Filipovich, A., Weisdorf, D., Pavletic, S. et al (2005). National Institutes of Health consensus development project on criteria for clinical trials in chronic graft-versus-host disease: I. Diagnosis and staging working group report. Biology of Blood and Marrow Transplantation, 11(12): 945-956.*
3. *Hematopoietic Cell Transplantation Registry - Japan Annual Report of Nationwide Survey 2022*
4. *News Release, March 22, 2024: Meiji Seika Pharma Presents Positive Findings from Phase III Study of Belumosudil, Selective ROCK2 Inhibitor, in Patients With Steroid-Dependent/Resistant cGVHD at JSTCT2024 in Japan*

Product Outline of "*REZUROCK® Tablets*"

Brand Name	*REZUROCK® Tablets*
Generic Name	Belumosudil Mesilate (JAN)
Indications	Chronic graft-versus-host disease after hematopoietic stem cell transplantation (in case of insufficient response to steroid therapy)
Use & Dosage	The standard dose for adults and children aged 12 years and older is 200 mg of belumosudil mesilate given orally once daily after a meal. Depending on concomitant medication, the dose can be increased to 200 mg twice daily if the effect is inadequate.
Date of Manufacturing and Marketing Approval	March 26, 2024
Date of NHI Reimbursement Price Listing	May 22, 2024
Date of Launch in Japan	May 22, 2024
NHI Reimbursement Price	30,525.90 JPY/tablet
Packaging	200 mg tablets in 30 count plastic bottle
Manufacturing and Marketing Authorization Holder	Meiji Seika Pharma Co., Ltd.
Distributor	Meiji Seika Pharma Co., Ltd.

*For further information, please refer to the package insert.