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ASIA EDITION

Thailand approves Meiji's REZUROCKÃ?Â® for treatment of chronic graft-versus-host disease

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REZUROCKÃ?Â® is the first approved and only selective therapy inhibiting ROCK2, a signaling pathway that plays a major role in the bodyÃ?Â¼s inflammatory and fibrotic responses

Japan's Meiji Seika Pharma has announced that its local subsidiary, Thai Meiji Pharmaceutical has received regulatory approval from the Food and Drug Administration, the Ministry of Public Health in Thailand for REZUROCK® (product name in Thailand, INN: belumosudil), a selective rho-associated, coiled-coil containing protein kinase 2 (ROCK2) inhibitor for the treatment of chronic graft-versus-host disease (chronic GVHD).

REZUROCK® will be marketed by Thai Meiji Pharmaceutical on behalf of Romeck Pharma LLC, the joint venture between Meiji Seika Pharma and Kadmon Corporation LLC, a Sanofi group company.

The approved indication for REZUROCK® is the 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. Chronic GVHD 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 transplantation. These enduring and deleterious features of chronic GVHD are driven by two major physiological responses: inflammation and fibrosis. Chronic GVHD is the leading cause of non-relapse mortality and morbidity in patients who have undergone an allogeneic stem cell transplant, with organ failure and infection as the leading causes.

REZUROCK® is the first approved and only selective therapy inhibiting ROCK2, a signaling pathway that plays a major role in the bodyÃ?Â¼s inflammatory and fibrotic responses. It is commercially available to prescribed patients with chronic GVHD in several countries, including the US, Canada, Great Britain, Japan, and South Korea, and has recently been approved in Taiwan. Romeck Pharma LLC has the exclusive right to develop and commercialise REZUROCK® in Japan and 12 Asian countries/regions.