

March 5, 2026

Meiji Seika Pharma Announces Initiation of Phase III Clinical Trial of REZUROCK® (Belumosudil), a Selective ROCK2 Inhibitor, in Japan for Chronic Lung Allograft Dysfunction

Meiji Seika Pharma Co., Ltd. (Headquarters: Tokyo, Japan; President and Representative Director: Toshiaki Nagasato) announced that the Phase III clinical trial in Japan ([iRCT2031250734](#)) of REZUROCK® (INN: belumosudil), a selective ROCK2 (rho-associated coiled-coil containing protein kinase 2) inhibitor, in patients with chronic lung allograft dysfunction (CLAD) has been initiated.

The clinical trial in Japan is conducted as part of a global Phase III study (multicenter, randomized, placebo-controlled, double-blind study: [NCT06082037](#)) run by Sanofi*, with fundamental support for the clinical trial by Meiji Seika Pharma. The trial aims to evaluate the safety, tolerability, and efficacy of REZUROCK® in Japanese patients with CLAD. Meiji Seika Pharma will, on behalf of Romeck Pharma LLC**, submit an application for approval and conduct sales of REZUROCK® for this indication in Japan upon successful completion of the clinical trial.

CLAD is a long-term complication after lung transplantation. It has been reported to develop in 43% of recipients at a median of 2.3 years post-transplant and to represent the leading cause of death following transplantation¹. CLAD comprises two phenotypes—bronchiolitis obliterans syndrome (BOS) and restrictive allograft syndrome (RAS)—which affect the airways and lung parenchyma and result in dyspnea. No established therapy exists for CLAD, although combination treatment with fluticasone, azithromycin, and montelukast (FAM) has been reported to benefit BOS; therapeutic options remain limited.

REZUROCK® is the first approved and only selective therapy inhibiting ROCK2, a signaling pathway that plays a major role in the body's inflammatory and fibrotic responses. It is commercially available as REZUROCK® by prescription for patients with chronic graft-versus-host disease (GVHD) in Japan and has recently been approved in Taiwan and Thailand, and is provided by Meiji Seika Pharma on behalf of Romeck Pharma LLC.

Meiji Seika Pharma will continue to work toward making REZUROCK® a new treatment option not only for chronic GVHD but also for CLAD, contributing to improved prognosis and quality of life for patients.

*Sanofi owns the global development and commercialization rights to REZUROCK® outside of Japan and 12 Asian countries/regions.

**Romeck Pharma LLC, a joint venture between Kadmon Corporation LLC, an affiliate of Sanofi, and Meiji Seika Pharma, has the exclusive right to develop and commercialize REZUROCK® in Japan and 12 Asian countries/regions.

- 1) Nykänen A, Raivio P, Peräkylä L, Stark C, Huuskonen A, Lemström K, Halme M, Hämmäinen P. Incidence and impact of chronic lung allograft dysfunction after lung transplantation: single-center 14-year experience. *Scand Cardiovasc J.* 2020 Jun;54(3):192-199. doi:10.1080/14017431.2020.1726444. Epub 2020 Mar 9.