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Meiji Seika Pharma Co., Ltd.

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

Meiji Seika Pharma Co., Ltd. (Headquarters: Tokyo, President and Representative Director: Daikichiro Kobayashi) today announced that positive findings from the phase III clinical trial of belumosudil (JAN: belumosudil mesylate, Development code: ME3208), a selective Rho-associated coiled-coil kinase 2 (ROCK2) inhibitor, in patients with steroid-dependent/resistant chronic graft versus host disease (cGVHD) conducted in Japan (jRCT2011210041) were presented on 22 March at the 46th JSTCT Annual Meeting (JSTC2024) of Japanese Society for Transplantation and Cellular Therapy held in Tokyo.

The abstract from the presentation is as follows:

Objective: *To report the primary analysis (cut-off date: February 23, 2023) from a multicenter, open-label, single-arm phase 3 study evaluating belumosudil mesylate (a selective Rho-associated coiled-coil kinase 2 [ROCK2] inhibitor) efficacy and safety in patients with steroid-dependent/resistant chronic graft versus host disease (cGVHD).*

Subjects and Methods: *Patients (≥12 years; allogeneic hematopoietic cell transplant; moderate to severe cGVHD; ≤3 prior systemic treatments) orally received belumosudil tablets 200 mg once daily after a meal. The primary endpoint was best overall response rate (ORR) at 24 weeks after enrollment of the last patient; if the lower limit of the confidence interval (CI) exceeded the threshold of 25%, statistical significance was determined. Adverse events (AEs) and adverse drug reactions (ADRs) were tabulated.*

Results: *In 21 patients evaluated (n=14 [66.7%] male; median age 50.0 years; median 2 prior treatments), cGVHD was steroid-dependent in 18 (85.7%) and severe in 9 (42.9%). Median belumosudil treatment duration was 9.2 months. The primary endpoint was met: best ORR at 24 weeks after enrollment of the last patient was 85.7% ([18/21 patients]; 95% CI: 63.66, 96.95). All were partial responses. Median time to response was 4.1 weeks; 13/18 patients (72.2%) had a sustained response for ≥20 wks. AEs occurred in 18/21 patients (85.7%), and ADRs in 8/21 (38.1%). There were no drug-related discontinuations or deaths. The most common AE was diarrhea (n=4 [19.0%]). The most common ADRs were herpes zoster and muscle spasms (n=2 [9.5%] each). Grade ≥3 AEs occurred in 6 patients (28.6%).*

Conclusion: *Belumosudil was effective in patients aged ≥12 years with cGVHD and an inadequate response to corticosteroids. No new safety concerns were identified compared with studies conducted overseas.*

Belumosudil (REZUROCK®) is commercially available to prescribed patients in several countries, including the US from August 2021 and in Canada and Great Britain from March 2023. In Japan and 12 Asian countries, Romeck Pharma LLC, the joint venture between Meiji and Kadmon Corporation LLC (Headquarters: New York City, U.S.A.), a Sanofi company, has the exclusive right to develop and commercialize REZUROCK®.

Meiji Seika Pharma will address unmet medical needs in the field of hematology by distributing REZUROCK® for the treatment of cGVHD in Japan.