

July 24, 2026

Meiji Seika Pharma: Global Phase III Clinical Trial of HBI-8000 in Advanced Melanoma Meets Primary Endpoint – Reported by HUYABIO International

Meiji Seika Pharma Co., Ltd. (headquartered in Tokyo, Japan; President and Representative Director: Toshiaki Nagasato) announced today that a global Phase III clinical trial ([NCT04674683](#)) conducted by HUYABIO International, LLC (headquartered in San Diego, CA; Chair and CEO: Dr. Mireille Gillings) evaluating HBI-8000 (INN: tucidinostat) in patients with advanced melanoma has met its primary endpoint. Meiji Seika Pharma supported the Japanese portion of the study ([jRCT2061220112](#)) and received the Orphan Drug Designation on November 27, 2025, from the Ministry of Health, Labour and Welfare for the treatment of unresectable malignant melanoma. Meiji Seika Pharma will apply for manufacturing and marketing approval in Japan for this indication.

The randomized global Phase III clinical trial enrolled 404 patients across 15 countries, including Japan. The study met its primary endpoint, with patients receiving HBI-8000 in combination with nivolumab achieving a median progression-free survival (PFS) of 11.7 months, compared with 7.4 months for patients receiving nivolumab plus placebo, a statistically significant improvement in PFS of 58%. Further statistical analysis is in progress to characterize the efficacy of HBI-8000. Data from this study will be presented by HUYABIO International at future medical meetings.

HBI-8000 is an orally available epigenetic immunomodulator. Meiji Seika Pharma is licensed by HUYABIO International to develop and sell the agent in Japan and seven Asian countries—South Korea, Thailand, Indonesia, Malaysia, the Philippines, Vietnam, and Singapore. In Japan, it was launched in October 2021 as “Hiyasta® Tablets 10 mg” for adult T-cell leukemia/lymphoma (ATLL), and the indication was later expanded to include peripheral T-cell lymphoma (PTCL). In November 2022, Meiji Seika Pharma assumed the manufacturing and marketing approval in Japan from Huya Japan LLC, a subsidiary of HUYABIO International.

Meiji Seika Pharma is committed to addressing unmet medical needs in hematology and oncology in Japan and across Asia by providing innovative therapies to patients.

References:

[Press release dated July 14, 2026, from HUYABIO International.](#)