

Meiji Seika Pharma Co., Ltd.

April 25, 2023

Meiji Seika Pharma Announces Initiation of Phase III Clinical Trial of HBI-8000 (Generic name: Tucidinostat) in Japanese Patients With Unresectable or Metastatic Melanoma

Meiji Seika Pharma Co., Ltd. (Headquarters: Tokyo, President and Representative Director: Daikichiro Kobayashi, “Meiji”) today announced that HUYABIO International, LLC (Headquarters: San Diego, California, United States, President, CEO & Executive Chair: Dr. Mireille Gillings, “HUYABIO”) initiates in Japan the Phase III trials of current ongoing global clinical trials of HBI-8000 for unresectable or metastatic melanoma (generic name: tucidinostat) in Japanese patients with unresectable or metastatic melanoma ([jRCT2061220112](#)).

This clinical trial is conducted by HUYABIO in Japan as a part of an International multicenter, randomized, double blinded, placebo-controlled Phase III registration study ([NCT04674683](#)) to evaluate the safety, tolerability and efficacy of HBI-8000 in combination with nivolumab in approximately 480 patients with unresectable or metastatic melanoma not previously treated with PD-1 or PD-L1 inhibitors in advanced setting.

HBI-8000 is an oral epigenetic immunomodulator. Meiji has the exclusive rights to develop and to market HBI-8000 in Japan and seven countries in Asia (South Korea, Thailand, Indonesia, Malaysia, Philippines, Vietnam and Singapore). Meiji has been marketing HBI-8000 (product name: Hiyasta[®] tablets 10mg) since its launch in October 2021 for relapsed or refractory adult T-cell leukemia-lymphoma (ATLL) and subsequently for relapsed or refractory peripheral T-cell lymphoma (PTCL), and has succeeded to receive the manufacture and market approval in Japan from Huya Japan G.K., a subsidiary of HUYABIO, in November 2022.

In addition to these disease conditions, Meiji is currently conducting a Phase Ib/II multi-regional, multi-center, single-arm, open-label study to evaluate the safety, tolerability and efficacy of HBI-8000 in combination with rituximab in patients with relapsed or refractory B-cell Non-Hodgkin’s Lymphoma in Japan ([jRCT2041210129](#)).

Meiji is currently developing HBI-8000 as a new therapy for hematologic malignancies and

melanoma to improve the prognosis and QOL of cancer patients.

1. About Hiyasta®

Hiyasta is an epigenetic immunomodulator with several approved indications including monotherapy for two subtypes of T-cell Non-Hodgkin's Lymphoma in Japan and in combination therapy for metastatic breast cancer in China. This oral agent targets class I histone deacetylases (HDAC) causing cell cycle arrest and tumor cell death as the mechanism underlying its single agent activity against lymphoma. The drug has also demonstrated immunomodulatory impact and is being tested in a global pivotal trial in melanoma combined with the checkpoint inhibitor nivolumab.

2. About HUYABIO International, LLC

HUYABIO is the leader in accelerating the global development of novel biopharmaceutical product opportunities originating in China enabling faster, more cost-effective and low-risk drug development in the global markets. Through extensive collaboration with biopharmaceutical, academic and commercial organizations, HUYABIO has built the largest China-sourced compound portfolio covering all therapeutic areas. Hiyasta®, the company's first commercial product, is marketed in Japan. With offices in the US, Japan, South Korea, Canada, Ireland and eight strategic locations across China, the Company has become a partner of choice to accelerate product development and maximize value globally. For more information please visit <https://huyabio.com/>.