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Meiji Seika Pharma Co., Ltd.

November 30, 2022

Meiji Seika Pharma Announces Transfer of Manufacturing and Marketing Approval for Hiyasta® Tablets 10mg, an Anti-Malignant Tumor Agent in Japan

Meiji Seika Pharma Co., Ltd. (Headquarters: Tokyo, President and Representative Director: Daikichiro Kobayashi, "Meiji") today announced the transfer of the manufacturing and marketing approval for Hiyasta® tablets 10mg (generic name: tucidinostat, "Hiyasta"), an anti-malignant tumor agent in Japan from Huya Japan G.K., a subsidiary of HUYABIO International, LLC* (Headquarters: San Diego, California, United States, President, CEO & Executive Chair: Dr. Mireille Gillings, "HUYABIO") as of 30th November, 2022.

With regard to Hiyasta, Huya Japan obtained the manufacturing and marketing approval in Japan in June 2021, and Meiji has been marketing it since its launch in October of the same year. By the transfer of the manufacturing and marketing approval, Meiji will take responsibility for stable supply and safety management, and will continue to provide information on proper use.

Hiyasta is an epigenetic immunomodulator with several approved indications including monotherapy for two subtypes of T-cell Non-Hodgkin's Lymphoma, i.e., relapsed or refractory adult T-cell leukemia-lymphoma (ATLL) and relapsed or refractory peripheral T-cell lymphoma (PTCL), in Japan. In addition to these indications, Meiji is currently conducting a Phase Ib/II clinical trial, as a multi-regional, multi-center, single-arm, open-label study to evaluate the safety, tolerability and efficacy of Hiyasta in combination with rituximab in patients with relapsed or refractory B-cell Non-Hodgkin's Lymphoma (jRCT2041210129). At the same time, HUYABIO is conducting a global Phase III study overseas in combination with nivolumab in untreated metastatic or unresectable malignant melanoma (NCT04674683).

Meiji strives to develop, promote proper use and provide information of Hiyasta so that it can be applied as a new treatment option for hematologic malignancy and tumors, and contribute to improving the prognosis and QOL of the patients.

*: For further information, please visit the website at: https://huyabio.com/

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 lower-risk drug development in the global markets. Through extensive collaboration with biopharmaceutical, academic and commercial organizations, it 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/.