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Meiji Seika Pharma Co., Ltd.

November 25, 2021

Approval for Additional Indication of Hiyasta® Tablets for Relapsed or Refractory PTCL Treatment in Japan

Meiji Seika Pharma Co., Ltd. (Headquarters: Tokyo, Japan, President and Representative Director: Daikichiro Kobayashi, "Meiji") today announced that an additional indication of Hiyasta® Tablets 10mg (generic name: tucidinostat, "Hiyasta") for relapsed or refractory peripheral T-cell lymphoma (PTCL) treatment has been approved in Japan as of 25th November, 2021. The application was submitted as of 22nd March, 2021, by Huya Japan G.K., a subsidiary of HUYABIO International, LLC (Headquarters: San Diego, California, United States, CEO and Executive Chair: Dr. Mireille Gillings, "HUYABIO").

Hiyasta is an oral epigenetic agent that regulates tumor cell growth, and is believed to have immunomodulatory properties as well. The approval of the additional indication has been made based on the result of Phase IIb clinical study conducted by HUYABIO to evaluate the efficacy and safety of Hiyasta in Japanese and South Korean patients with relapsed or refractory PTCL.

Hiyasta was already approved for relapsed or refractory adult T-cell leukemia-lymphoma (ATLL) in Japan as of 23rd June, and Meiji has been marketing the product since 20th October, 2021.
The Ministry of Health, Labour and Welfare in Japan granted to Hiyasta orphan drug designation for PTCL and relapsed or refractory ATLL. At the same time, HUYABIO is conducting the overseas multinational phase III clinical study of Hiyasta, in combination with antitumor agent, in patient with untreated metastatic or unresectable malignant melanoma.

Under the collaboration agreement entered into between HUYABIO and Meiji in December 2019, Meiji has an exclusive right to market Hiyasta in Japan, as well as exclusive rights to develop and market in seven countries in Asia (South Korea, Thailand, Indonesia, Malaysia, Philippines, Vietnam and Singapore). Meiji strives to promote proper use and provide information of Hiyasta so that it can be applied as a new treatment option for ATLL and contribute to improving the QOL and prognosis of the patients.

1. About Hiyasta

Hiyasta is an epigenetic immunomodulator approved for the treatment of relapsed or refractory PTCL and metastatic breast cancer in China. This oral agent targets histone deacetylase (HDAC1, HDAC2 and HDAC3 in Class I, as well as HDAC10 in Class IIb) enzymes to induce cell cycle arrest, apoptosis and suppress the tumor growth. The detailed mechanism of actions are being elucidated.

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. Through extensive collaboration with biopharmaceutical, academic and commercial organizations, it has built the largest China-sourced compound portfolio covering all therapeutic areas. 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 www.huyabio.com.