ENGLISH TRANSLATION

7th April 2021

Application for Additional Indication of HBI-8000 Submitted for Relapsed or Refractory PTCL Treatment

Meiji Seika Pharma Co., Ltd. (Headquarters: Tokyo, Japan, President and Representative Director: Daikichiro Kobayashi, "Meiji") today announced that an application for additional indication of an epigenetic immunomodulator HBI-8000 (JAN/USAN/INN: tucidinostat) for relapsed and refractory peripheral T-cell lymphoma (PTCL) treatment in Japan was submitted as of 22nd March by Huya Japan G.K., a subsidiary of HUYA Bioscience International, LLC (Headquarters: San Diego, California, United States, CEO and Executive Chair: Dr. Mireille Gillings, "HUYABIO").

HBI-8000 is an oral epigenetic agent that regulates tumor cell growth, and is believed to have immunomodulatory properties as well. This application is based on the result of Phase II clinical study conducted by HUYABIO to evaluate the efficacy and safety of HBI-8000 in Japanese and South Korean patients with relapsed or refractory PTCL. In the meantime, HUYABIO has also submitted an application seeking manufacturing and marketing approval of HBI-8000 for relapsed or refractory adult T-cell leukemia-lymphoma (ATLL) in Japan. The Ministry of Health, Labour and Welfare granted to HBI-8000 orphan drug designation in Japan for HBI-8000 for relapsed and refractory ATLL and PTCL. HUYABIO will complete the phase I/II clinical study of HBI-8000 in solid tumors in the United States.

Dr. Mireille Gillings, CEO & Executive Chair of HUYABIO said, "This is an important Public Health contribution as R/R PTCL patients will have an effective treatment alternative. It is our second regulatory submission for drug approval in Japan in 6 months and we continue to work hard to benefit patients with difficult to treat diseases."

Under the collaboration agreement entered into between HUYABIO and Meiji in December 2019, Meiji has an exclusive right to market HBI-8000 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 is committed to providing new treatment options for patients with PTCL and ATLL in order to further contribute to addressing unmet medical needs that exist in the treatment of hematological malignancy.

1. About HBI-8000

HBI-8000 is an epigenetic immunomodulator approved for the treatment of lymphoma and metastatic breast cancer in China. This oral agent targets class I histone deacetylase (HDAC) enzymes to induce cell cycle arrest, suppress the expression of a number of oncogenes and modulate of the acetylation of PD-L1 to enhance the activity of immune checkpoint inhibitors. The drug also has immunomodulatory impact by increasing the efficacy of checkpoint inhibitors in preclinical animal models.

2. About HUYA Bioscience 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.