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Meiji Seika Pharma Co., Ltd.

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Marketing Approval of HBI-8000 (Tucidinostat) for Relapsed or Refractory ATLL Treatment in Japan

Meiji Seika Pharma Co., Ltd. (Headquarters: Tokyo, Japan, President and Representative Director: Daikichiro Kobayashi, “Meiji”) today announced that an epigenetic immunomodulator HBI-8000 (JAN/USAN/INN: tucidinostat) has been approved for relapsed or refractory adult T-cell leukemia-lymphoma (ATLL) treatment in Japan, submitted as of 30th September 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”).

HBI-8000 is an oral epigenetic agent that regulates tumor cell growth, and is believed to have immunomodulatory properties as well. This approval is based on the result of Phase IIb clinical study conducted by HUYABIO to evaluate the efficacy and safety of HBI-8000 in patients with relapsed or refractory ATLL in Japan. In the meantime, HUYABIO has also submitted an application seeking manufacturing and marketing approval of HBI-8000 for relapsed or refractory peripheral T-cell lymphoma (PTCL) in Japan.
The Ministry of Health, Labour and Welfare granted to HBI-8000 an orphan drug designation in Japan for PTCL and relapsed or refractory ATLL. 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 first regulatory approval for our lead oncology drug, HBI-8000 is a major milestone for HUYABIO. The durability and strong immuno-oncology properties of HBI-8000 set the stage for improved cancer treatment of both solid and liquid tumors. Synergy with PD-1/PD-L1 inhibitors hold particular promise for major solid tumor advances."

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) and suppresses the expression of the viral oncogene HTLV-I bZIP factor, nuclear factor kappa-light-chain-enhancer of activated B cells (NF-κB) and the inflammasome in ATLL cells. Furthermore, HBI-8000 may induce latent viral antigen expression making ATLL cells more sensitive to immune cytotoxicity targeting.

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, HUYABIO has become a partner of choice to accelerate product development and maximize value globally. For more information please visit www.huyabio.com.