ENGLISH TRANSLATION

7 October 2020

Application for Manufacturing and Marketing Approval of HBI-8000 Submitted for Relapsed or Refractory ATLL Treatment

Meiji Seika Pharma Co., Ltd. (Headquarters: Tokyo, Japan, President and Representative Director: Daikichiro Kobayashi, "Meiji") today announced that an application seeking manufacturing and marketing approval of an epigenetic immunomodulator HBI-8000 (JAN/USAN/INN: tucidinostat) for relapsed and refractory adult T-cell leukemia-lymphoma (ATLL) treatment in Japan was submitted as of 30th September 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").

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).

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 patients with relapsed or refractory ATLL. In the meantime, HUYABIO is also conducting the phase II clinical trial of HBI-8000 for relapsed or refractory peripheral T-cell lymphoma (PTCL) in Japan and Korea. 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.

"We are excited about the partnership with Meiji. HBI-8000 is a breakthrough product with immuno-oncology properties and this success for treating ATLL is the first step in expanding the availability of innovative cancer therapies" said Dr. Mireille Gillings, CEO and Executive Chair.

Meiji is committed to providing new treatment options for patients with ATLL and PTCL 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 orally bioavailable novel epigenetic drug and a member of the benzamide class of histone deacetylase (HDAC) inhibitors. HBI-8000 inhibits Class I HDAC1, HDAC2, HDAC3, as well as Class IIb HDAC10 at nanomolar concentrations and stimulates accumulation of acetylated histones H3 and H4 in tumor cells. This alters the expression of several proteins involved in processes that arrest the growth of cancer cells and increases tumor immunity by controlling the nuclear transport of PD-L1 which regulates the expression of immune genes in the tumor microenvironment. Evidence suggests that combinations of HBI-8000 increases the efficacy of other cancer agents such as immune checkpoint inhibitors.

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 in international markets. 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.