

9 January 2020

Meiji and HUYABIO Enter into Exclusive Distribution, License and Collaboration Agreement of HBI-8000 for ATLL and PTCL Treatment in Japan and Certain Asian Countries

Meiji Seika Pharma Co., Ltd. (Headquarters: Tokyo, Japan, President and Representative Director: Daikichiro Kobayashi, “Meiji”) today announced that it has entered into an exclusive distribution, license and collaboration agreement for the epigenetic immunomodulator, HBI-8000, from HUYA Bioscience International, LLC (Headquarters: San Diego, California, United States, CEO and Executive Chair: Dr. Mireille Gillings, “HUYABIO”).

Under the agreement, Meiji has exclusive rights to market HBI-8000 in Japan, as well as exclusive rights to develop and market in the seven licensed territories in Asia (South Korea, Thailand, Indonesia, Malaysia, Philippines, Vietnam and Singapore). According to the agreement, Meiji will pay HUYABIO upfront, development and commercial milestone payments as well as royalties, respectively.

HBI-8000 is an oral epigenetic agent that regulates tumor cell growth, and is believed to have immunomodulatory properties as well. HUYABIO is preparing to submit application for the regulatory approval of HBI-8000 for relapsed or refractory adult T-cell leukemia-lymphoma (ATLL), and conducting the phase II clinical trial of HBI-8000 for relapsed or refractory peripheral T-cell lymphoma (PTCL) in Japan, respectively. Based on clinical results, the regulatory authority granted HBI-8000 orphan drug designation in Japan for PTCL. Meanwhile, HUYABIO will complete the phase I/II clinical study of HBI-8000 in solid tumors in the United States.

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 HUYA Bioscience International, LLC

HUYA Bioscience International, LLC (Headquarters: United States, “HUYABIO”) is the leader in enabling and accelerating the global development of novel pharmaceutical product opportunities originating in China. Extensive collaborations are established with Chinese biopharmaceutical, academic and commercial organizations to speed development and value creation in worldwide markets for China-sourced product candidates. With the largest Chinese compound portfolio covering all therapeutic areas, HUYABIO has emerged as the partner-of-choice for maximizing the value of biopharmaceutical innovation in China. HUYABIO has offices in the United States, Japan, South Korea and eight strategic locations across China. With the largest team of scientists working with Chinese innovators, HUYABIO identifies and advances promising drug candidates globally. For more information, please visit www.huyabio.com

2. 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 cancer-associated 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, increase tumor immunity and change the tumor microenvironment. Evidence suggests that this mechanism increases the efficacy of other cancer agents such as checkpoint inhibitors.