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# EISAI ACQUIRES EXCLUSIVE LICENSE FROM HUYA BIOSCIENCE INTERNATIONAL TO DEVELOP AND MARKET HDAC INHIBITOR HBI-8000 IN JAPAN AND OTHER ASIAN COUNTRIES

Eisai Co., Ltd. (Headquarters: Tokyo, CEO: Haruo Naito, "Eisai") announced today that Eisai has entered into an exclusive license agreement with HUYA Bioscience International, LLC (Headquarters: San Diego, California, United States, President, CEO, Executive Chairman & Founder: Dr. Mireille Gillings, "HUYA") to develop and market the oral histone deacetylase (HDAC) inhibitor HBI-8000 in Japan, South Korea, Thailand, Malaysia, Indonesia, Philippines, Vietnam and Singapore.

HBI-8000 is an oral HDAC inhibitor approved in China for use in the treatment of peripheral T-cell lymphoma (PTCL). Non-clinical data suggest HBI-8000 has epigenetic properties that work to regulate tumor cell growth, and the agent is believed to have immunomodulatory properties as well. HBI-8000 is at the clinical stage of testing in Japan as a treatment for PTCL, a type of non-Hodgkin's lymphoma, under orphan drug designation from the regulatory authority in Japan. Meanwhile, a Phase I clinical study of the agent in solid tumors has been completed in the United States.

Under the agreement, Eisai has exclusive rights to develop and market HBI-8000 in the licensed territories. However, for PTCL and adult T-cell leukemia-lymphoma, HUYA will complete development of the agent for these indications and Eisai will be responsible for commercialization. According to the agreement, Eisai will pay HUYA upfront, development and commercial milestone payments as well as royalties over the term of the license, respectively.

Eisai positions oncology as a key franchise area, and is committed to providing new treatment options for patients with cancer in order to further contribute to addressing unmet medical needs that exist in the treatment of cancer as well as increase the benefits provided to patients and their families.

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### [Notes to editors]

## 1. About HUYA Bioscience International, LLC

HUYA Bioscience International, LLC (Headquarters: United States, "HUYA") 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, HUYA has emerged as the partner-of-choice for maximizing the value of biopharmaceutical innovation in China. HUYA 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, HUYA identifies and advances promising drug candidates globally. HUYA received the Asia-Pacific Stevie<sup>®</sup> Award in the Health Products and Services & Pharmaceuticals category and Dr. Mireille Gillings received the Gold Stevie Award in the Woman of the Year 2015 American Business Award category. For more information, please visit <u>www.huyabio.com</u>

#### 2. About HBI-8000

HBI-8000 is a member of the benzamide class of histone deacetylase (HDAC) inhibitors designed to block the catalytic pocket of Class I HDACs. HBI-8000 is an orally bioavailable, low-nanomolar inhibitor of cancer-associated HDAC enzymes with favorable pharmacology and safety profiles. 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. Studies with human-derived tumor cell lines suggest that HBI-8000 inhibits the growth of many tumor cell lines via multiple mechanisms of action, including epigenetic regulation of tumor cell growth and apoptosis as well as immunomodulatory effects regulating antitumor activity.

To date, HBI-8000 has been dosed in various types of hematological and solid tumors in several clinical trials, including a Phase I trial completed in the United States. HBI-8000 is approved for the treatment of peripheral T-cell lymphoma (PTCL) in China. A Phase I clinical study of the agent in non-Hodgkin's lymphoma is underway in Japan under orphan drug designation as a treatment for PTCL by the regulatory authority in Japan.

# 3. About HDAC

Removing acetyl groups from lysine amino acids on histones to encourage stronger binding of chromatin structures to suppress gene transcription, and adding acetyl groups to weaken binding of chromatin structures to promote transcriptional activity play an important role in regulation of gene transcription on histones. HDAC are enzymes that remove acetyl groups from lysine amino acids on histones, and it is thought that by inhibiting HDAC to allow acetyl groups to accumulate on histones and relax chromatin structures promotes gene transcription activity. In tumor cells, inhibiting HDAC suppresses tumor growth by facilitating the transcriptional activity of cancer suppressing genes and inducing both apoptosis in tumor cells as well as cell cycle arrest.

#### 4. About Epigenetics

The study of epigenetics involves research into the processes that bring about changes in gene expression without modifying DNA sequencing. It is said that tumor cells have an accumulation of various epigenetic defects in addition to genetic aberrations.