BIOWORLD™ TODAY
THE DAILY BIOPHARMACEUTICAL NEWS SOURCE
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FEBRUARY 3, 2016
VOLUME 27, NO. 22
SPECIAL REPRINT

Huya, Eisai join forces in $280M deal for HDAC inhibitor HBI-8000

By Cornelia Zou, Staff Writer

HONG KONG – A promising cancer orphan drug could soon be available in a string of major and emerging Asian markets, marking the next step in a multinational partnership for global commercialization and research.

U.S.-China biopharma company Huya Bioscience International LLC said it inked a licensing agreement with Japanese pharmaceutical company Eisai Co. Ltd. (TYO:4523) for the commercialization of Huya's HBI-8000. The initial target for commercialization is eight Asian countries, namely Japan, South Korea, Thailand, Malaysia, Indonesia, Philippines, Vietnam and Singapore.

A class I-selective oral histone deacetylase (HDAC) inhibitor, HBI-8000 is approved in China for the treatment of peripheral T-cell lymphoma and appears to have promising prospects for the oncology market. Data show the drug can regulate tumor cell growth and also has immunomodulatory properties.

HBI-8000 inhibits class I HDAC1, HDAC2, HDAC3, as well as class IIb HDAC10 at nanomolar concentrations that are associated with cancer. It stimulates accumulation of acetylated histones H3 and H4 in tumor cells. It has been shown to inhibit the growth of various tumor cell lines in various ways, including epigenetic regulation of tumor cell growth and apoptosis, immunomodulatory effects regulating antitumor activity and the repression of genes associated with drug resistance.

"A phase I trial conducted by Huya is ongoing in Japan, among patients with peripheral T-cell lymphoma as well as adult T-cell leukemia-lymphoma," Eisai's spokeswoman, Carole Suzuki, told *BioWorld Today*.

"The drug has been granted an orphan drug designation by the Japanese regulatory authority," added Suzuki. "For other indications and territories, we will consider the development plans in the future."

HBI-8000 is at different stages of development for non-Hodgkin's lymphoma (NHL) in Japan and solid tumors in the U.S. The product was granted orphan drug designation by Japan's Ministry of Health, Labour and Welfare last December.

"Our excitement about HBI-8000 increases almost daily, particularly as we are also demonstrating important immunological properties for this oral product with exemplary safety. Patients with both liquid and solid tumors will benefit as our precision medicine team develops 8000 to its full potential," said Huya's CEO and executive chairman, Mireille Gillings.

Gillings said she believes HBI-8000 "may have the potential to be a blockbuster".

Huya also has plans to launch a registration trial for HBI-8000 in lymphoma, Gillings told *BioWorld Today*. "We aim to launch the products within the next several years."

Under the new agreement, Huya will be responsible for HBI-8000's development for the NHL indication in Japan, while Eisai will hold on to exclusive rights to develop future indications in the eight countries. Eisai will pay Huya an up-front fee and milestones of up to $280 million plus royalties upon the marketing of the drug. Huya will be responsible for manufacture.

The deal will make it possible for Huya to use the Tripartite Cooperation Treaty to leverage clinical data from Asia to expand into developed markets like Japan and South Korea.

The treaty links Japan, South Korea and China and facilitates the use of data from one country to develop and ultimately commercialize drugs in another. In December, Huya claimed to have become the first company to use the treaty to push forward product development in Japan using data from China. That month, the company also opened an office in South Korea and signed a deal with the Korean Drug Development Fund. (See *BioWorld Today*, Dec. 9, 2015.)

"Eisai's global strength in oncology will help ensure the drug's path to regulatory approval," said Gillings.

Ultimately, the deal should pave the way for Eisai and Huya to commercialize HBI-8000 to "bring about benefits for patients with cancer," said Terushige like, chief product creation officer of Eisai Product Creation Systems.

Headquartered in Tokyo, Eisai focuses on the development of new treatment options for oncology. The company's pipeline includes 11 oncology drugs in various development stages.

Eisai's most advanced cancer agent Halaven (eribulin) is in phase III trials in China, Japan, the U.S. and the EU for different types of cancers. Halaven got a regulatory approval for the treatment of soft tissue sarcoma in the U.S. last month and is pending approval from Japan and the EU. Eisai is also working with Merck & Co. Inc. to develop its triple-negative breast cancer indication.

Another Eisai drug, Lenvima (lenvatinib), a multiple receptor tyrosine kinase inhibitor, is in phase I, II and III studies for different indications in different countries.

The company's humanized antifolate receptor alpha monoclonal antibody farletuzumab is currently in phase II studies in Japan, the U.S. and the EU.

Eisai also has eight neurology drugs under development. Eisai's stock price jumped 7.2 percent from ¥7,325 (US$61) to ¥7,774 on Feb. 2, the day after the announcement of the licensing deal.

Huya, for its part, counts HBI-3000 and HBI-3802 as other key cardiovascular candidates. The first is a multi-ion channel blocker to treat cardiac arrhythmia that is in phase II trials in China.

HBI-3802, or cardiogenin, is in preclinical studies and has the potential to regenerate cardiac muscle cells and reduce morbidity due to acute myocardial infarction, the company said.