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HUYA Bioscience International (HUYA) has completed the first cohort in a Phase 1 clinical trial in Japan of its cancer drug HBI-8000, a novel oral histone deacetylase (HDAC) inhibitor.

This follows acceptance by the Pharmaceutical and Medical Devices Agency (PMDA) of the company's accelerated development strategy in Japan.

The Phase 1 open-label, dose escalation trial is evaluating the safety and pharmacokinetics of HBI-8000 in Japanese patients with non Hodgkin's lymphoma. The first cohort received HBI-8000 tablets twice weekly, with no dose-limiting toxicities observed. The second cohort is now underway with a higher dose.

The trial is designed to establish a maximum tolerated dose (MTD) to proceed to Phase 2 trials for the treatment of adult T-cell leukemia/lymphoma (ATL) and peripheral T-cell lymphoma (PTCL) in Japan.

The clinical development of HBI-8000 in Japan leverages clinical data from Chinese clinical trials through the Tripartite Cooperation on Health between China, South Korea and Japan.

Shenzhen Chipscreen Biosciences recently announced the approval of chidamide in China as the world's first oral HDAC inhibitor for the treatment of relapsed or refractory PTCL. HUYA holds exclusive rights to chidamide (HBI-8000) worldwide,

excluding China, and is developing the compound for hematological malignancies and solid tumors.

HBI-8000 (chidamide) 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 favourable 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 have demonstrated 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, immunomodulatory effects such as activation of NK- and CD8 T-cell-mediated antitumor activity, as well as repression of genes associated with drug resistance.

To date, HBI-8000 has been dosed in various types of hematological and solid tumors in several clinical trials, including a Phase 1 trial completed in the United States.