Press Release

May 20, 2021

H3 Biomedicine Announces Presentation of Four Abstracts at the 2021 American Society of Clinical Oncology (ASCO) Annual Meeting

Cambridge, MA — H3 Biomedicine Inc. (H3), a U.S.-based precision medicine research & development subsidiary of Eisai Co., Ltd., today announced the presentation of four posters providing updated investigational data on its H3B-6545 clinical program for breast cancer and its H3B-6527 clinical program for hepatocellular carcinoma at the 2021 American Society of Clinical Oncology (ASCO) Annual Meeting, being held virtually June 4–8, 2021.

"We continue to be encouraged by the insights gained through our evaluation of genomically and clinically defined patient populations in these two oncology programs in areas of tremendous unmet medical need," said Antonio Gualberto, MD, PhD, Chief Medical Officer of H3. "We look forward to further highlighting our innovative, data-driven approach to precision oncology research and to showcasing the potential clinical benefit of our product candidates for patients with cancer at ASCO 2021."

The investigational clinical data abstracts published online today for the H3B-6545 and H3B-6527 studies reflect data as of March 31, 2021 and Jan 04, 2021, respectively. Updated results from both studies will be presented at ASCO.

H3's ASCO abstract titles are as follows:

H3B-6545

Abstract Number: 1018

Title: Phase I/II Study of H3B-6545, a Novel Selective Estrogen Receptor Covalent Antagonist (SERCA), in Estrogen Receptor Positive (ER+), Human Epidermal Growth Factor Receptor 2 Negative (HER2-) Advanced Breast Cancer
Poster Discussion Session: Breast Cancer – Metastatic
Presenter: Erika P. Hamilton, Sarah Cannon Research Institute, Tennessee Oncology

Abstract Number: e13025

Title: Phase 1b Study of H3B-6545 in Combination with Palbociclib in Women with Metastatic Estrogen Receptor–positive (ER+), Human Epidermal Growth Factor Receptor 2 (HER2)-negative Breast Cancer
Poster Session: Breast Cancer – Metastatic (Online Publication Only)
Presenter: Stephen R.D. Johnston

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Abstract Number: e13022

Title: Relative Bioavailability of H3B-6545 Tablets vs Capsules and Drug-Drug Interaction between H3B-6545 and Pantoprazole
Poster Session: Breast Cancer – Metastatic (Online Publication Only)
Presenter: Alan Xiao

H3B-6527

Abstract Number: 4090

Title: Phase 1 Study of H3B-6527 in Hepatocellular Carcinoma (HCC) or Intrahepatic Cholangiocarcinoma (ICC)
Poster Session: Gastrointestinal Cancer – Gastroesophageal, Pancreatic and Hepatobiliary
Presenter: Teresa Macarulla

ABOUT H3B-6545

Estrogen receptor alpha (ERα) plays an important oncogenic role in the genesis and progression of luminal breast cancers and historically has been a target of endocrine therapies. However, recently, hotspot mutations in ERα have been detected in nearly 30% of endocrine-therapy resistant metastases. Functional studies have shown that these ERα mutations can confer ligand-independent activation of the ERα pathway and can promote partial resistance to existing classes of ER-directed therapies. H3B-6545, a first-in-class small molecule selective estrogen receptor covalent antagonist (SERCA) demonstrates activity in tumor models that harbor wild-type or mutant ERα. H3B-6545 activity against ERα mutants resistant to standard therapy provides an opportunity to target a currently unmet medical need both as a single agent and in combination with other breast cancer therapies.

ABOUT H3B-6527

Receptor tyrosine kinases (RTKs) can be dysregulated in cancer cells and can frequently promote abnormally rapid tumor growth and development. Hepatocellular carcinoma (HCC) can be driven in this way by hyperactivation of the fibroblast growth factor 19 (FGF19)/fibroblast growth factor receptor 4 (FGFR4) pathway. H3B-6527 is a selective, orally bioavailable, and covalent inhibitor of FGFR4 that has demonstrated tumor regression in several preclinical models of HCC. H3B-6527 is being tested specifically in patients with FGFR4-dysregulated advanced HCC.

The abstracts discuss investigational uses of agents in development and are not intended to convey conclusions about efficacy or safety. There is no guarantee that such investigational agents will successfully complete clinical development or gain health authority approval.

ABOUT H3 BIOMEDICINE INC.

H3 Biomedicine Inc., the U.S.-based precision oncology research and development subsidiary of Eisai Co., Ltd., is solely focused on advancing drugs from bench to bedside. Uniquely positioned to integrate real-world clinical evidence with the latest advances in cancer genomics, H3 is developing a pipeline of highly targeted, breakthrough medicines that have the potential to impact the future of cancer care and treatment. Learn more at H3Biomedicine.com.

H3 Biomedicine
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