Press Release

December 8, 2021

H3 Biomedicine Presents Investigational Data Update on H3B-6545 for Treatment of Locally Advanced or Metastatic Estrogen Receptor- positive, HER2-negative Breast Cancer at San Antonio Breast Cancer Symposium

Cambridge, MA — H3 Biomedicine Inc. (H3), a U.S.-based precision medicine research & development subsidiary of Eisai Co., Ltd., today announced the presentation of two posters at the 2021 San Antonio Breast Cancer Symposium (SABCS) being held in a hybrid format on December 7- 10, 2021. The presentations include interim investigational data from H3's ongoing clinical development program, H3B-6545, a potential first-in-class, orally available Selective ERα Covalent Antagonist (SERCA), in women with ER-positive, HER2-negative breast cancer.

"At H3, we are developing a pipeline of targeted medicines with the potential to impact the future of cancer treatment," said Ping Zhu, Ph.D., President and Chief Scientific Officer of H3. "Our ongoing clinical study of H3B-6545 is evaluating its potential to address current unmet medical needs in breast cancer either as a single agent or in combination with therapies such as palbociclib. We look forward to showcasing its progress at SABCS 2021."

H3B-6545 PRESENTATIONS

Abstract Number: 976

Title: 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 – A Phase II Study
Program Number: P1-17-10 Poster Session: 1
Date and Time: Wednesday, December 8, 2021, 7:00am–8:30am CT
Presenter: Erika P. Hamilton, Sarah Cannon Research Institute, Tennessee Oncology

Abstract Number: 1166

Title: H3B-6545 in Combination with Palbociclib in Women with Metastatic Estrogen Receptor-Positive (ER+), Human Epidermal Growth Factor Receptor 2 (HER2)-Negative Breast Cancer, Phase 1b Study Program Number: P1-17-03
Poster Session: 1
Date and Time: Wednesday, December 8, 2021, 7:00am–8:30am CT Presenter: Stephen Johnston, Royal Marsden NHS FDN Trust, London, UK

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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.

This release discusses investigational uses of agents in development and is 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.

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