Foghorn Therapeutics Provides Update on FHD-286 Clinical Development Program and Strategic Priorities

Dec 16, 2024

Objective clinical responses by standard response criteria observed in Phase 1 dose escalation trial for FHD-286 in combination with decitabine in patients with relapsed and/or refractory AML; efficacy threshold not achieved to support continued development by Foghorn alone

Company to prioritize investment into proprietary pipeline and Lilly collaboration programs, including the clinical-stage selective SMARCA2 (BRM) inhibitor, FHD-909 (LY4050784)

As of September 30, 2024, the Company had $267.4 million in cash, cash equivalents and marketable securities; cash runway supports Company into 2027

CAMBRIDGE, Mass., Dec. 16, 2024 (GLOBE NEWSWIRE) -- Foghorn® Therapeutics Inc. (Nasdaq: FHTX), a clinical-stage biotechnology company pioneering a new class of medicines to treat serious diseases by correcting abnormal gene expression, announced today that it has made the decision to discontinue the independent development of FHD-286 in combination with decitabine in patients with relapsed and/or refractory acute myeloid leukemia (AML). Foghorn is evaluating partnerships and ISTs (Investigator Sponsored Trials) to advance FHD-286. The Company will prioritize its proprietary pipeline and Lilly collaboration programs, including the clinical-stage selective SMARCA2 (BRM) inhibitor FHD-909 (LY4050784).

As of September 30, 2024, the Company had $267.4 million in cash, cash equivalents and marketable securities. Its cash runway supports the Company into 2027.

In the Phase 1 dose escalation trial of FHD-286 in combination with decitabine in relapsed and/or refractory AML, objective clinical responses were observed by standard response criteria. However, the observed response rate did not meet the Company's threshold to continue development by Foghorn alone. Foghorn expects to report the results at a medical conference in 2025.

"While clinical responses were observed for FHD-286, we will prioritize investment into our proprietary pipeline, including our Selective CBP program, Selective EP300 program, and ARID1B program, as well as our Lilly collaboration, including the clinical development of FHD-909." said Adrian Gottschalk, President and Chief Executive Officer of Foghorn. "Our pipeline of potential medicines represents significant opportunities in oncology with the potential for therapeutic expansion. We want to thank the clinical investigators, the patients, and their families for their participation in the FHD-286 clinical trial."

About FHD-286

FHD-286 is a highly potent, first-in-class, selective, allosteric, and orally available small-molecule, enzymatic inhibitor of SMARCA2 (BRM) and SMARCA4 (BRG1), two highly similar proteins that are the ATPases, or the catalytic engines, of the BAF complex, one of the key regulators within the chromatin regulatory system. In preclinical studies, FHD-286 has shown anti-tumor activity across a broad range of malignancies, including both hematologic and solid tumors.

About AML

Adult acute myeloid leukemia (AML) is a cancer of the blood and bone marrow and the most common type of acute leukemia in adults. AML is a diverse disease associated with multiple genetic mutations. It is diagnosed in about 20,000 people every year in the United States.

About Foghorn Therapeutics

Foghorn® Therapeutics is discovering and developing a novel class of medicines targeting genetically determined dependencies within the chromatin regulatory system. Through its proprietary scalable Gene Traffic Control® platform, Foghorn is systematically studying, identifying, and validating potential drug targets within the chromatin regulatory system. The Company is developing multiple product candidates in oncology. Visit our website at www.foghorntx.com for more information on the Company, and follow us on X (formerly Twitter) and LinkedIn.

Forward-Looking Statements

This press release contains "forward-looking statements." Forward-looking statements include statements regarding the Company's clinical trials, including its ongoing Phase 1 trial of FHD-909 in SMARCA4-mutated cancers, preclinical product candidates, expected timing of clinical data, expected cash runway, expected timing of regulatory filings, and research efforts and other statements identified by words such as "could," "may," "might," "will," "likely," "anticipates," "intends," "plans," "seeks," "believes," "estimates," "expects," "continues," "projects" and similar references to future periods. Forward-looking statements are based on our current expectations and assumptions regarding capital market conditions, our business, the economy and other future conditions. Because forward-looking statements relate to the future, by their nature, they are subject to inherent

uncertainties, risks and changes in circumstances that are difficult to predict. As a result, actual results may differ materially from those contemplated by the forward-looking statements. Important factors that could cause actual results to differ materially from those in the forward-looking statements include regional, national or global political, economic, business, competitive, market and regulatory conditions, including risks relating to our clinical trials and other factors set forth under the heading “Risk Factors” in the Company’s Annual Report on Form 10-K for the year ended December 31, 2023, as filed with the Securities and Exchange Commission. Any forward-looking statement made in this press release speaks only as of the date on which it is made.

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