Foghorn Therapeutics Provides Update on Phase 1 Study of FHD-286 in Relapsed and/or Refractory AML and MDS

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CAMBRIDGE, Mass., May 19, 2022 (GLOBE NEWSWIRE) -- Foghorn® Therapeutics Inc. (Nasdaq: FHTX), a clinical stage biotechnology company pioneering a new class of medicines that modulate gene expression through selectively targeting the chromatin regulatory system, today announced the Food and Drug Administration (FDA) has placed the Phase 1 dose escalation study of FHD-286 in relapsed and/or refractory acute myelogenous leukemia (AML) and myelodysplastic syndrome (MDS) on a partial clinical hold. The partial clinical hold was initiated by the FDA following the report of a recent death that occurred in a subject with potential differentiation syndrome. Differentiation syndrome is associated with AML/MDS therapeutics that induce differentiation, an effect that is believed to be on-target for the proposed mechanism of action for FHD-286. The FDA has requested a review of the safety database, risk mitigation strategies and a breakdown of clinical activity across dose levels.

Patients currently enrolled in the dose escalation Phase 1 study of FHD-286 in AML/MDS and benefitting from treatment may continue to receive treatment, although no new patients can be enrolled until the partial clinical hold is resolved. The partial clinical hold does not apply to the FHD-286 dose escalation Phase 1 study in metastatic uveal melanoma (mUM), with enrollment in that study continuing per protocol.

“Patient safety remains our top priority. We appreciate the dialogue with the FDA and will work diligently with the Agency to resolve the partial clinical hold in AML/MDS as soon as possible,” said Foghorn CEO Adrian Gottschalk.

Until Foghorn has resolved the partial clinical hold for the AML/MDS study, the Company is suspending guidance on the timing of the data release for the dose escalation phase of the FHD-286 program.

About FHD-286

FHD-286 is a highly potent, selective, allosteric and orally available, small-molecule, enzymatic inhibitor of BRG1 and BRM, two highly similar proteins that are the ATPases, or the catalytic engines across all forms of the BAF complex, one of the key regulators of 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. To learn more about these studies please visit ClinicalTrials.gov. (Link here for metastatic uveal melanoma and here for AML and MDS).

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 Uveal Melanoma

Uveal (intraocular) melanoma (UM) is a rare eye cancer that forms from cells that make melanin in the iris, ciliary body, and choroid. It is the most common eye cancer in adults. It is diagnosed in about 2,000 adults every year in the United States and occurs most often in lightly pigmented individuals with a median age of 55 years. However, it can occur in all races and at any age. UM metastasizes in approximately 50% of cases, leading to very poor prognosis.

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.

Forward-Looking Statements

This press release contains “forward-looking statements.” Forward-looking statements include, but are not limited to, statements concerning the Company’s clinical programs for FHD-286, including potential resolution of the partial clinical hold and anticipated timing of release of initial clinical data. Forward-looking statements include statements regarding the Company’s clinical trials, product candidates 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, 2021 and subsequent Quarterly Reports on Form 10-Q, 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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