Foghorn Therapeutics Announces Clinical Data from Phase 1 Study of FHD-286 in Metastatic Uveal Melanoma

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- Clinical data support safety and tolerability profile of FHD-286, a highly potent, selective, allosteric, oral, small molecule inhibitor of BRG1/BRM

- Clinical activity observed in late-line metastatic uveal melanoma includes nine patients with stable disease and one patient with a confirmed partial response

- Foghorn does not plan to advance FHD-286 in uveal melanoma

- Foghorn anticipates initiating a FHD-286 combination study in relapsed/refractory AML during the third quarter of 2023

CAMBRIDGE, Mass., June 28, 2023 (GLOBE NEWSWIRE) -- Foghorn® Therapeutics Inc. (Nasdaq: FHTX), a clinical-stage biotechnology company pioneering a new class of medicines that treat serious disease by correcting abnormal gene expression, today announced data from the Phase 1 dose escalation safety study of FHD-286 in metastatic uveal melanoma (mUM). These data reinforce the safety and tolerability profile of FHD-286. At this time, the company does not plan to advance FHD-286 in uveal melanoma.

“The clinical data further support the safety and tolerability of FHD-286 and build on the previously disclosed AML/MDS data. In the study, nine patients had stable disease and one patient had a durable partial response,” said Adrian Gottschalk, President and Chief Executive Officer of Foghorn. “However, Foghorn does not plan to pursue this indication on its own. We plan to initiate dosing the FHD-286 combination study in relapsed/refractory AML during the third quarter of 2023 and continue to invest in our promising pre-clinical programs such as Selective-BRM, CBP, EP300, and ARID1B.”

FHD-286 Phase 1 Dose Escalation Study Data in Metastatic Uveal Melanoma

The trial evaluated 73 metastatic uveal melanoma patients who had been treated with a median of two prior therapies across nine different cohorts. The doses evaluated included four continuous daily doses: 2.5mg (n=2), 5.0mg (n=12), 7.5mg (n=17), and 10.0mg (n=9); and five intermittent 1 week on/1 week off dose cohorts: 10.0mg (n=10), 15.0mg (n=9), 17.5mg (n=3), 20.0mg (n=5), and 22.5mg (n=6).

Clinical data seen in the Phase 1 dose escalation study reinforced the safety and tolerability profile of FHD-286. The most common treatment-related adverse events were dysgeusia, fatigue, AST increase, nausea/vomiting, dry mouth, and rash. The most common treatment-related grade 3 events or higher included anemia, asthenia, ALP increase, hypokalemia, muscular weakness, and rash.

Forty-seven of the 73 patients on study had target lesions for evaluation. One patient had a durable partial response and remained on treatment for over 16 months, and nine patients had stable disease. Tumor reductions in target lesions were also observed in eight patients. The clinical activity seen in the study was further supported by reductions in circulating tumor DNA (ctDNA). Preliminary data on immune modulation markers in the tumor microenvironment also support a combination path forward with checkpoint inhibitors.

The Company plans to present the full results at a future scientific meeting.

Foghorn plans to dose the first patient in a Phase 1 study of FHD-286 in combination with decitabine or cytarabine in relapsed and/or refractory AML patients in the third quarter of 2023.

About FHD-286

FHD-286 is a highly potent, selective, allosteric and orally available, small-molecule, enzymatic inhibitor of BRG1 (SMARCA4) and BRM (SMARCA2), 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. FHD-286 is being developed for relapsed and/or refractory AML, and the company plans to commence a Phase 1 study, in combination with decitabine or cytarabine, in the third quarter of 2023.

About Uveal Melanoma

Uveal (intraocular) melanoma is a rare eye cancer that forms from cells that make melanin in the iris, ciliary body, and choroid, and 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. This press release refers to data gathered on an ongoing basis from our open-label Phase 1 trial in FHD-286 for uveal melanoma.

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 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 Phase 1 study of FHD-286 in combination with decitabine or cytarabine in relapsed and/or refractory AML patients, 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, 2022 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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