Foghorn Therapeutics Announces Dosing of First Patient in First-in-Human Clinical Program of FHD-286

May 17, 2021

- First clinical candidate of a new class of therapeutics directly targeting the chromatin regulatory system

- FHD-286 is a highly potent, selective, allosteric, oral, small molecule inhibitor of BRG1/BRM

CAMBRIDGE, Mass., May 17, 2021 (GLOBE NEWSWIRE) -- Foghorn Therapeutics Inc. (Nasdaq: FHTX), a company pioneering the discovery and development of a new class of medicines targeting genetically determined dependencies within the chromatin regulatory system, today announced that the first patient has been dosed in a first-in-human clinical trial of FHD-286 in metastatic uveal melanoma (mUM). A separate clinical study of FHD-286 in relapsed/refractory acute myelogenous leukemia (AML) is also underway.

FHD-286 is a selective inhibitor of the BAF chromatin remodeling complex ATPases BRG1 and BRM, and the first program in Foghorn's diverse pipeline of novel drug candidates targeting genetically determined dependencies within the chromatin regulatory system. FHD-286 is not only the company's first clinical stage program, the company believes it is also the first drug candidate directly targeting the chromatin regulatory system to enter clinical trials.

"Initiating our first clinical studies of FHD-286 is an important milestone for Foghorn, validating the potential of our Gene Traffic Control® platform to develop novel therapeutics and improve the lives of people with devastating diseases," said Sam Agresta M.D., M.P.H., Chief Medical Officer of Foghorn Therapeutics. "People with metastatic uveal melanoma and relapsed/refractory AML as well as MDS have limited treatment options. Based on our precise understanding of the dependencies that these cancers have on the chromatin regulatory system, we believe our dual inhibitor, FHD-286, has the potential to alter the course of disease of these people with uveal melanoma and AML as well as other diseases. In addition, we are continuing to study the effects of BRG1/BRM inhibition in other solid and hematologic tumor types for potential indication expansion in the future."

Both the FHD-286 metastatic uveal melanoma and AML (including MDS), clinical trials are first-in-human and first-in-class. Each is an open-label, monotherapy, dose-escalation study evaluating the safety, pharmacokinetics, pharmacodynamics and clinical activity of FHD-286 administered orally. To learn more about the first-in-human clinical trial of FHD-286 in metastatic uveal melanoma, please visit here.

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.

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 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" regarding the Company's clinical programs for FHD-286. Forward-looking

statements include statements regarding the Company's clinical trial, 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 risk regarding the timing of filing an IND for our product candidates and other factors set forth under the heading "Risk Factors" in the Company's Form 10-K. Any forward-looking statement made in this press release speaks only as of the date on which it is made.

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