Foghorn Therapeutics Announces First Patient Dosed in First-in-Human Clinical Trial of FHD-609

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FHD-609 is a first-in-class, highly potent and selective protein degrader of BRD9

Foghorn's first protein degrader program to enter the clinic; continues pre-clinical work on other protein degrader programs for broad range of cancers

Significant unmet need in synovial sarcoma with limited therapeutic options

CAMBRIDGE, Mass., Aug. 23, 2021 (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 that the first patient has been dosed in a first-in-human clinical trial of FHD-609, which is being developed as a treatment for synovial sarcoma. With an initial focus in oncology, Foghorn's Gene Traffic Control Platform ® and resulting broad pipeline have the potential to transform the lives of people suffering from a wide spectrum of diseases.

"FHD-609 is our first protein degrader to enter the clinic, marking an exciting milestone for this program and further validating the potential of our Gene Traffic Control platform and our capabilities of creating precision medicines based on targeted protein degradation," said Adrian Gottschalk, President and Chief Executive Officer. "Foghorn has a broad pipeline of protein degrader programs, and we continue to advance these precision medicines towards clinical development."

FHD-609 is a potent, selective protein degrader of BRD9 (bromodomain-containing protein 9), a subunit of ncBAF (non-canonical BAF complex). Substantially all synovial sarcoma cancers contain a translocation, a type of mutation between a BAF subunit gene SS18 and another set of genes SSX. These mutations render the cancer genetically dependent upon BRD9, what is commonly referred to as a synthetic lethal relationship.

FHD-609 is the second program to enter the clinic from Foghorn's diverse pipeline targeting genetically determined dependencies within the chromatin regulatory system. In May 2021, the company announced the first patient dosed in first-in-human clinical trials of FHD-286, a selective inhibitor of the BAF chromatin remodeling complex ATPases BRG1 and BRM, in metastatic uveal melanoma (mUM) relapsed/refractory acute myelogenous leukemia (AML) and myelodysplastic syndromes (MDS). To learn more about these studies in FHD-286, please visit ClinicalTrials.gov. (Link here for mUM and here for AML and MDS)

Sam Agresta M.D., M.P.H., Chief Medical Officer, said, "Synovial sarcoma is a rare, often aggressive malignancy with limited therapeutic options. In preclinical studies, FHD-609 has been shown to selectively degrade BRD9, taking advantage of a synthetic lethal relationship with the SS18-SSX translocation. We look forward to initial clinical data in the first half of 2022."

The FHD-609 clinical trial in advanced synovial sarcoma is first-in-human and first-in-class. The open-label, monotherapy, dose-escalation and dose-expansion study will evaluate the safety, pharmacokinetics, pharmacodynamics and clinical activity of FHD-609 administered intravenously. To learn more about the first-in-human clinical trial of FHD-609 in synovial sarcoma, please visit ClinicalTrials.gov.

About FHD-609

FHD-609 is a potent, selective, intravenously administered protein degrader of BRD9, a component of the ncBAF complex. Preclinical studies have demonstrated tumor growth inhibition in synovial sarcoma, a cancer genetically dependent on BRD9.

About Synovial Sarcoma

Synovial sarcoma is a rare, often aggressive soft tissue sarcoma that originates from different types of soft tissue, including muscle or ligaments. Synovial sarcoma can occur at any age but is most common among adolescents and young adults. It represents around 5-10% of all soft tissue sarcomas, with ~800 new cases each year in the United States. Surgery remains the most effective treatment for synovial sarcoma, and there are limited therapeutic treatment options.

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-609 and FHD-286, including the results therefrom and the timing of clinical data relating thereto, and its research pipeline. 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 risk regarding the timing of regulatory filings relating to 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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