Foghorn Therapeutics Announces First Patient Dosed with First-in-Class Oral SMARCA2 Selective Inhibitor FHD-909 in a Phase 1 Trial for SMARCA4 Mutated Solid Tumors

October 10, 2024

Primary target patient population for the FHD-909 Phase 1 trial is non-small cell lung cancer (NSCLC)

Lilly leads the clinical development of the Phase 1 trial

Foghorn's selective SMARCA2 oncology program is part of a U.S. 50/50 co-development and co-commercialization collaboration with Lilly

CAMBRIDGE, Mass., Oct. 10, 2024 (GLOBE NEWSWIRE) -- October 10, 2024 -- Foghorn® Therapeutics Inc. (Nasdaq: FHTX), a clinical-stage biotechnology company pioneering a new class of medicines that treat serious diseases by correcting abnormal gene expression, today announced that the first patient has been dosed with FHD-909 (LY4050784) in the Phase 1 trial for SMARCA4 (BRG1) mutated cancers, with non-small cell lung cancer (NSCLC) as the primary target patient population. FHD-909 is a first-in-class oral, highly potent compound that demonstrates high selectivity for SMARCA2 (BRM) over SMARCA4, a closely related protein.

"FHD-909 is the first SMARCA2 selective inhibitor to enter the clinic. Dosing the first patient marks an important milestone for the program and our collaboration with Lilly," said Adrian Gottschalk, President and Chief Executive Officer of Foghorn. "FHD-909 has high selectivity over closely related SMARCA4, offering a promising synthetic lethality strategy for prevalent SMARCA4 mutations and their sensitivity to SMARCA2 inhibition in NSCLC and other solid tumors. We look forward to continued advancement of FHD-909 in partnership with Lilly."

A Phase 1 open-label, multicenter trial will assess the safety, tolerability and initial efficacy of FHD-909 in patients with locally advanced or metastatic solid tumors harboring a SMARCA4 alteration.

Preclinical studies support that FHD-909 is a potent and selective SMARCA2 inhibitor with robust anti-tumor monotherapy activity. *In vivo*, FHD-909 has demonstrated favorable tolerability with dose-dependent modulation of SMARCA2 target genes, as well as robust and dose-dependent tumor growth inhibition and regression as a monotherapy in SMARCA2 mutant xenograft mouse models.

In December 2021, Foghorn announced a strategic collaboration with Lilly to create novel oncology medicines. The collaboration includes a U.S. 50/50 co-development and co-commercialization agreement for Foghorn's Selective SMARCA2 oncology program and an additional undisclosed oncology target. The collaboration also includes three discovery programs using Foghorn's proprietary Gene Traffic Control ® platform.

To learn more about the Phase 1 trial of FHD-909, please visit ClinicalTrials.gov.

About FHD-909
FHD-909 (LY4050784) is a potent, first-in-class, allosteric and orally available small molecule that selectively inhibits the ATPase activity of SMARCA2 (BRM) over its closely related paralog SMARCA4 (BRG1), two proteins that are the catalytic engines across all forms of the BAF complex, one of the key regulators of the chromatin regulatory system. In preclinical studies, tumors with mutations in SMARCA4 rely on SMARCA2 for BAF function. FHD-909 has shown significant anti-tumor activity across multiple SMARCA4 mutant lung tumor models.

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, product candidates and research efforts, including statements relating to FHD-909, 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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