Foghorn Therapeutics Highlights Clinical Program Updates and Research Progress and Provides Strategic Objectives for 2024

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- FHD-286 combination study in AML continues to progress in the clinic with data anticipated in the second half of 2024; preclinical combination data with FHD-286 and tyrosine kinase inhibitors (TKIs) in EGFR/KRAS resistance anticipated by the second quarter of 2024

- BRM selective inhibitor and degrader programs advancing in partnership with Loxo@Lilly

- Preclinical efficacy and safety demonstrated with selective EP300 and CBP programs; additional preclinical data anticipated in the second quarter of 2024; targeting IND enabling studies for CBP before end of 2024

- Foghorn anticipates at least six new INDs targeting significant oncology patient populations over the next four years, reflecting the continued productivity of its precision medicine platform

- Cash, cash equivalents, and marketable securities of $259.9 million, as of September 30, 2023, provides cash runway into the first half of 2026

CAMBRIDGE, Mass., Jan. 08, 2024 (GLOBE NEWSWIRE) -- 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 its strategic objectives for 2024.

“We enter 2024 with several important milestones ahead of us. We anticipate data from our Phase 1 combination study of FHD-286 in AML in the second half of the year and look forward to continued progress with our unique pipeline, including our BRM selective inhibitor and degrader programs in collaboration with Loxo@Lilly,” said Adrian Gottschalk, President and Chief Executive Officer. “We have made significant progress with our preclinical programs, including our selective EP300, CBP and ARID1B degrader programs and are getting ready to share more preclinical data in the first half of the year. This will also include preclinical combination data of FHD-286 with tyrosine kinase inhibitors of EGFR and KRAS. Over the next four years, we anticipate the filing of at least six new INDs, reflecting the productivity of our precision medicine platform. This is all supported by our cash and equivalents position of approximately $259.9 million as of September 30, 2023.”

- **FHD-286**. FHD-286 is a potent, selective inhibitor of the BRG1 and BRM subunits of the BAF chromatin remodeling complex where dependency on BRG1/BRM is well-established preclinically with multiple tumor types, including acute myelogenous leukemia (AML)/myelodysplastic syndrome (MDS), non–small cell lung cancer (NSCLC) and prostate cancer.
    - **AML Update.** Foghorn commenced a Phase 1 study of FHD-286 in combination with decitabine or low-dose cytarabine (LDAC) in relapsed and/or refractory AML patients, with the first patient dosed during the third quarter of 2023. The first clinical data are expected in the second half of 2024.
    - **TKI Resistance.** Recently published data, along with Foghorn’s work, suggest that FHD-286 may play an important role in overcoming resistance in EGFR/KRAS tumors. The company is conducting preclinical work to further explore the opportunity.
- **Differentiated Pipeline Advancement.** Foghorn continues to expand its platform and pipeline. The Company anticipates the potential for six new investigational new drug (IND) applications in the next four years. The Company continues to progress programs for multiple targets that include chromatin remodeling complexes, transcription factors, helicases and other chromatin-related factors. These targets include selective BRM* and wholly owned programs including CBP, EP300, and ARID1B, as well as other undisclosed targets, which combined could address more than 20 tumor types impacting more than 500,000 new patients annually.
    - **Selective EP300 and Selective CBP programs.** Foghorn presented new preclinical data for its EP300 and CBP selective degrader programs at Hanson Wade’s 6th Annual Targeted Protein Degradation Summit on October 31, 2023.
        - EP300 selective degraders showed potent cellular antiproliferation and in vivo tumor growth inhibition in an AR+ enzalutamide prostate in vivo model.
        - CBP selective degraders demonstrated significant tumor growth inhibition in a colorectal cancer in vivo model. Antiproliferative effects were also observed for numerous cancer cell lines, including colorectal, gastric and bladder cancers.
        - At preclinical efficacious doses, neither the EP300 nor the CBP selective degraders caused thrombocytopenia, a commonly observed safety liability for dual CBP/EP300 inhibitors.

- Additional preclinical data will be presented in the first half of 2024.

- ***Loxo@Lilly Collaboration.** Foghorn is engaged in a strategic collaboration with Loxo@Lilly and continues to advance the BRM selective inhibitor and degrader programs along with other undisclosed programs.

- **Strong Balance Sheet and Cash Runway**. As of September 30, 2023, the Company had $259.9 million in cash, cash equivalents and marketable securities providing cash runway into the first half of 2026.

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 X (formerly Twitter) and LinkedIn.

Forward-Looking Statements

This press release contains "forward-looking statements." Forward-looking statements are 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, including statements regarding potential combination trials involving FHD-286, the progress of our Loxo@Lilly collaboration, and our proprietary pre-clinical programs. 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, 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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