



FOR IMMEDIATE RELEASE

Exosome Diagnostics Launches CLIA-Certified Laboratory in Cambridge, Mass.

Company centralizing U.S. operations ahead of cancer liquid biopsy test launches in 2015

CAMBRIDGE, Mass., August 12, 2015 – Exosome Diagnostics, Inc., a developer of revolutionary, biofluid-based molecular diagnostics, today announced that it has opened a Clinical Laboratory Improvement Amendments (CLIA)-certified laboratory in Cambridge, Mass. The state-of-the-art clinical services laboratory will manage analysis and reporting for several liquid biopsy tests that the company plans to launch this year for prostate, lung and other solid tumor cancers. These novel diagnostics will help clinicians detect disease sooner and obtain access to real-time molecular insights that can help better inform treatment decisions for patients with cancer and other serious diseases.

“Exosome Diagnostics is dedicated to effectively solving challenges in health care and overcoming barriers to disease detection, monitoring and treatment,” said Thomas McLain, chief executive officer of Exosome Diagnostics. “We are taking this important step to centralize our operations at our U.S. corporate headquarters in Cambridge as we work to seamlessly launch new molecular diagnostics, while also accelerating the application of our technology platform to other important disease areas.”

Exosome Diagnostics is currently developing a suite of innovative plasma- and urine-based liquid biopsies that analyze exosomal RNA (exoRNA) for biomarkers. The company’s technology platform is uniquely versatile, offering the additional capability to simultaneously isolate and analyze exoRNA and cell-free DNA (cfDNA) to enhance detection of rare mutations. Exosomes are messengers released by all living cells into biofluids, such as plasma/serum, urine, cerebrospinal fluid and saliva. Exosomes contain RNA, DNA and proteins from their cell of origin. Exosome Diagnostics’ technology platform can achieve real-time access to comprehensive molecular information about cells in the body without direct access to the actual cells.

In 2015, Exosome Diagnostics plans to launch two blood-based lung cancer liquid biopsy tests to help clinicians detect the presence of the ALK and T790M mutations in order to match patients to appropriate targeted therapies or clinical trials and avoid therapies to which patients are not likely to respond. The company also plans to commercialize a urine-based liquid biopsy test designed to reduce unnecessary prostate biopsies by accurately predicting which patients do not have high-grade prostate cancer. These tests are expected to launch initially as lab developed tests (LDTs) and be analyzed exclusively out of Exosome Diagnostics’ CLIA lab. The company anticipates launching *in vitro* diagnostic (IVD) test kits at a later date, which could be analyzed at other reference laboratories as well.

To support pharmaceutical companies' clinical trial recruitment and monitoring, Exosome Diagnostics also plans to launch a solid tumor panel this year to enable rapid identification of eligible patients and longitudinal and serial molecular monitoring throughout the clinical trial process. The panel is expected to target 26 of the most important genes and approximately 1000 associated mutations in the most significant pathways implicated in lung, colon and breast cancers, including EGFR/MAPK and PI3K. The panel, as well as the T790M diagnostic, are built on the company's exoRNA plus cfDNA platform to provide highly sensitive detection of rare mutations that may be missed by cfDNA-only liquid biopsy platforms.

Coinciding with the Cambridge laboratory's opening, Exosome Diagnostics has closed operations at its existing CLIA laboratory in St. Paul, MN. The new Cambridge-based CLIA laboratory has taken over the functional operations of the St. Paul lab, and expanded its efforts to enable clinicians to access its molecular diagnostics to support detection, monitoring and treatment stratification.

Exosome Diagnostics' European operations are based in Munich; the laboratory there will be instrumental when the company's diagnostic tests launch in Europe, which is expected in 2016. The systems and processes at the Cambridge and Munich labs will be standardized, and both labs are expected to be fully operational in all phases of diagnostic development, from discovery through commercialization.

About Exosome Diagnostics

Exosome Diagnostics is a privately held company focused on developing and commercializing revolutionary biofluid-based diagnostics to deliver personalized precision healthcare that improves lives. The company's novel exosome-based technology platform can yield comprehensive and dynamic molecular insights to transform how cancer and other serious diseases are detected, diagnosed, treated and monitored. Visit www.exosomedx.com to learn more.

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