



Exosome Diagnostics Launches Clinical Commercialization Program for the Research Market

CAMBRIDGE, Mass., November 24, 2015 – Exosome Diagnostics, the developer of the leading liquid biopsy platform that enables non-invasive diagnosis of disease states, aiming to obviate the need for tissue biopsies, has announced its “Academic Bench to Clinical Diagnostics” (A to D) Assay Commercialization Program.

The “A to D” program will provide academic and clinical researchers a means for bringing their biomarkers and assays to the clinical laboratory while simultaneously utilizing the experience of the Exosome Diagnostics team to navigate the regulatory approval, reimbursement, commercialization and business development processes. Researchers are developing novel biomarkers and assays with the company’s patented exosome isolation and RNA extraction technology using the exoRNeasy research kits marketed by QIAGEN. The exoRNeasy kit enables a convenient, robust and high yield isolation of exosomal RNA from blood.

Under this program researchers will now be able to bring their assays to Exosome Diagnostics for further validation by leveraging the company’s expertise in exosome isolation and analysis and development on the company’s proprietary clinical testing platforms, ExoLution™ for RNA-based biomarkers and assays and ExoLutionPlus™ for the addition of cell-free DNA, or cfDNA, for increased sensitivity of rare mutations when necessary. The ExoLution platforms have been developed and will be manufactured under cGMP to enable the exosome biomarkers to be extracted for clinical use, and are only available directly through Exosome Diagnostics. Simultaneously the Regulatory Affairs team at Exosome Diagnostics will work with the appropriate regulatory agencies worldwide to ensure the fastest route for diagnostics approval.

“Based on the data presented at scientific venues and in the literature, we have developed a sensitive and robust platform for liquid biopsy diagnostic assay development, regardless of the body fluid,” stated Johan Skog, Ph.D., Chief Scientific Officer at Exosome Diagnostics. “By working with researchers using exoRNeasy research kits, our labs at Exosome Diagnostics can increase assay sensitivity and ensure proper validation for diagnostic approval on our ExoLution and ExoLutionPlus platforms.”

“Over seven years ago we announced the discovery that extracellular vesicles, usually termed exosomes, contain RNA that can be used diagnostically, and that they are able to mediate communication among cells. This pioneering work at MGH advanced the understanding of the role exosomes play in cancer and all diseases,” stated Xandra Breakefield, PhD, Professor of Neurology, Harvard Medical School and Geneticist, Neurology and Radiology Services,

Massachusetts General Hospital. “Building on that discovery, Exosome Diagnostics developed a proprietary and efficient technology for isolating exosomes from any biofluid and extracting and analyzing the RNA, DNA and protein inside the exosomes. This has advanced scientific and clinical understanding of exosomes and is leading to the identification of novel biomarkers to detect disease and monitor patients. Now Exosome Diagnostics is partnering with academia to drive advances in patient care. Their bench to bedside model will help researchers move their discoveries to market. This unique, innovative program will help drive advances in our understanding of disease and access to biomarkers and diagnostic tests that improve patient outcomes.”

“QIAGEN’s success as the exclusive distributor for the exoRNeasy kit, for research applications only, is building a worldwide user base for our technology in leading academic institutions. In most cases biomarker signatures developed through academic research stops at the point of publication as the validation process and the regulatory process is time consuming and complex. Furthermore, tests cannot be launched to the clinical market using the research only platform marketed by QIAGEN. We are launching our novel ‘A to D’ program to provide academic researchers with a conduit to bring their biomarkers and assays into the clinic for the benefit of patients,” stated John Boyce, President and CEO of Exosome Diagnostics. “We will work with these inventors to further develop the sensitivity of their assay by migrating their tests from the exoRNeasy research platform to our proprietary clinical platform, ExoLution. We will also provide the expertise needed to advance the diagnostic test through the regulatory approval and reimbursement processes,” Boyce continued. “Our ‘A to D’ program will allow researchers to break through the regulatory and commercialization barriers that too often prevent important discoveries from reaching patients. At the same time, it will expand the pipeline of liquid biopsy assays for Exosome Diagnostics.”

Information on the “A to D” program will be provided on the Exosome Diagnostics website, and will be continuously updated over the coming weeks. Inquiries about the program may be directed to: atod@exosomedx.com.

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, ExoLution™, 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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