Exosome Diagnostics Obtains ISO 15189 for Its Munich Laboratory

The company is growing its clinical laboratories due to demand for its liquid biopsy tests

CAMBRIDGE, MA- January 18, 2017 - Exosome Diagnostics, Inc. announced that it has received ISO 15189 certification for its Munich laboratory, thereby paving the way to process clinical samples in Asia, Europe, the Middle East, and Russia, more efficiently. Combined with the company's CLIA certified Cambridge laboratory, the Munich laboratory and offices will serve as an integral part of the company's diagnostic strategy to better the lives of patients worldwide.

"Working closely with the appropriate regulatory agencies, Exosome Dx adheres to the strictest standards to provide the highest quality of diagnostic tests to clinicians," stated Raaj Venkatesan, Head of Regulatory Affairs at Exosome Diagnostics. "Exosome Diagnostics has built a team of dedicated regulatory professionals and scientists that has put quality and process as its number one priority," Venkatesan continued.

In September 2016, Exosome Diagnostics launched its flagship diagnostic test for prostate cancer, ExoDx Prostate Intelliscore (EPI), to determine whether a patient who presented with a PSA in the gray zone needed to proceed with a biopsy. In the United States each year, approximately one million prostate biopsies are performed with up to 80 percent of the results indicating no cancer, or a low-grade cancer that could instead be monitored under a watchful waiting or active surveillance program. The EPI test was designed to reduce the number of unnecessary prostate biopsies and the associated overtreatment of low-grade disease. Complications associated with unnecessary prostate tissue biopsies range from discomfort and temporary incontinence or impotence, to hospitalization for serious infections in three to four percent of patients.

"In order to keep up with the demand for EPI in the United States, the company is increasing its clinical laboratory space by four-fold within the next few months," stated Elizabeth Cormier, Head of Commercial Diagnostics at Exosome Diagnostics. "As we grow our commercial distribution capabilities worldwide, we anticipate demand in Europe to be on par with the United States, therefore the Munich clinical laboratory will be an essential component for satisfying that capacity," Cormier continued.

Over the last year, the company has built an experienced Regulatory division and Commercial Diagnostics division in order to work with clinicians to deliver high quality diagnostic tests, while responsibly working with the FDA and appropriate regulatory agencies worldwide.

"Exosome Diagnostics has developed an extremely sensitive liquid biopsy platform, ancillary technologies and a proprietary informatics pipeline, that is able to rapidly develop robust diagnostic tests for early stage disease detection," stated John Boyce, President and CEO of Exosome Diagnostics. "Over the next year the company will realize the fruits of its labor from an in house program, by launching a number of tests for early stage disease detection," Boyce continued. "The Munich laboratory is an essential part of the company's strategy and I am extremely proud of the professional team in Germany that worked so diligently with the Regulatory department to achieve this certification," stated Boyce.

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 diagnosed, treated and monitored. Visit www.exosomedx.com to learn more. ExoDx is a registered trademark of Exosome Diagnostics, Inc. Exosome Diagnostics and ExoLution are unregistered trademarks of Exosome Diagnostics, Inc.

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