Accelerate Diagnostics Reports Positive Results From Pilot Study of Its Investigational ID/AST System and Blood Culture Assay Kit and Initiation of Trial to Support FDA Clearance

TUCSON, Ariz., Dec. 2, 2015 (GLOBE NEWSWIRE) -- Accelerate Diagnostics, Inc. announced positive findings from a multicenter pilot study to evaluate external performance of its ID/AST System and Blood Culture Assay Kit. Based on the results of the study, the company also announced the initiation of its clinical trial for submission to the U.S. Food and Drug Administration.

The Accelerate ID/AST System is being investigated for use as a fully integrated, easy-to-use platform that provides high-speed identification (ID) and antimicrobial susceptibility testing (AST) of pathogens directly from patient samples. The platform has the potential to enable laboratories to provide critical results in hours instead of days. The Accelerate ID/AST Blood Culture Assay Kit is being investigated for its ability to provide ID and AST results for patients suspected of bacteremia or fungemia, both life-threatening conditions with high morbidity and mortality risk. This first sample kit consists of a highly multiplexed panel of more than 150 individual assays, which have the potential to support clinicians in prescribing optimal antibiotic therapy for patients with bloodstream infections. The final number of assays included in the kit will depend on the results of the trial and FDA review of each individual assay for marketing clearance.

"We believe the results of the study are promising and support the potential of the system and kit in a clinical setting," said Beth Lingenfelter, Head of Clinical and Scientific Affairs at Accelerate Diagnostics. "Across 273 samples, the overall sensitivity and specificity for identification was 96.6% and 99.4% respectively; while essential agreement (EA) and categorical agreement (CA) for AST averaged 94.3% and 91.3% across all drugs." Time to result for ID was approximately 75 minutes, with AST results available about five hours later. Based on preclinical work, the company believes AST results for the clinical product will be available between approximately three and five hours after ID, depending on the bacteria being tested.1

The study included 10 external sites and the analysis of 146 fresh de-identified positive blood culture samples from patients and 127 samples seeded with challenging bacterial or fungal isolates. Enrollment for the pilot study followed a protocol similar to the company's larger clinical trial which is planned to expand to 11 external sites. Upon successful completion of the trial, the company plans to submit a de novo 510(k) application seeking premarket clearance for the system and kit. The company expects that commercial launch of an FDA-cleared Accelerate ID/AST System and Blood Culture Assay Kit could occur as early as the third quarter of 2016.

"We are encouraged by the results of the pilot study," said Lawrence Mehren, President and CEO at Accelerate Diagnostics. "While small, the pilot, combined with the extensive external preclinical work we have done, provides additional confidence in our investigational system, our first investigational test kit, and our trial intended to support FDA clearance."

1Times quoted are post blood culture; which, based on the pilot study, can take as few as 6 hours and as many as 96 hours. Based on literature searches, Accelerate estimates the median time to blood culture positivity is approximately 12 hours.

About Accelerate Diagnostics, Inc.

Accelerate Diagnostics, Inc. (Nasdaq:AXDX), is an in vitro diagnostics company dedicated to providing solutions for the global challenge of antibiotic resistant organisms. The company's investigational ID/AST platform utilizes proprietary molecular and phenotypic detection technologies which have the potential to significantly decrease the time to result while achieving high sensitivity and specificity. For more information about the company and products visit www.acceleratediagnostics.com.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Safe Harbor Provisions of the Private Securities Litigation Reform Act of 1995, including, without limitation, statements regarding the company's initiation of the trial intended to support FDA clearance, marketing clearance by the FDA and the timing thereof, the launch of an FDA-cleared product, the potential of the ID/AST System and Blood Culture Assay Kit, and the company's prospects for future growth. These statements in this announcement are made based on the company's current beliefs, known events and circumstances at the time of publication and, as such, are subject in the future to unforeseen risks and uncertainties that could cause the company's results of operations, performance and achievements to differ materially from current expectations expressed in, or implied by, these forward-looking statements. These risks include potential factors which may lead to delays in the initiation or completion of the trial intended to support FDA clearance, delays in the submission to

the FDA or review of the submission by the FDA, and delays in the launch of an FDA-cleared product. For a full discussion of the company's risks and uncertainties, which could cause actual results to differ from those contained in the forward-looking statements, see "Risk Factors" in Part 1, Item A in the company's most recent Annual Report on Form 10-K, filed with the SEC on February 26, 2015. In addition, the company's forward-looking statements could be affected by general industry and market conditions. Except as required by federal securities laws, the company undertakes no obligation to update or revise these forward-looking statements to reflect new events, uncertainties or other contingencies.

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