July 11, 2016

Accelerate Diagnostics Submits De Novo Request to FDA for Accelerate Pheno™ System and Accelerate PhenoTest™ BC kit

TUCSON, Ariz., July 11, 2016 (GLOBE NEWSWIRE) -- Accelerate Diagnostics, Inc. ("Accelerate") announced today the submission of a *De Novo* request for Evaluation of Automatic Class III Designation to the U.S. Food and Drug Administration (FDA) for its Accelerate Pheno™ system and Accelerate PhenoTest™ BC kit for positive blood culture samples.

The fully automated system provides high-speed identification (ID) and antimicrobial susceptibility testing (AST) of pathogens from patient samples faster than conventional methods. In recently completed marketing studies, the system and kit saved more than 40 hours as compared to standard of care methods; creating the potential to expedite optimal antimicrobial therapy for patients suspected of bacteremia or fungemia, both life-threatening conditions with high morbidity and mortality risk.

The Accelerate PhenoTest™ BC kit consists of a highly multiplexed panel of assays targeting the most prevalent microorganisms and the antimicrobial agents typically used to treat them. Accelerate anticipates launching the BC kit with 140 individual assays. The final number of assays included in the kit distributed in the U.S. will depend on the review of each individual assay for marketing authorization by the FDA.

The *De Novo* request, sent Friday evening to the FDA, is supported by a recently completed clinical study including more than 1,800 samples across 13 study sites. Overall results across all assays from the study showed 97.4% sensitivity and 99.3% specificity for ID results and 95.1% essential agreement and 96.0% categorical agreement for AST.

About Accelerate Diagnostics, Inc.

Accelerate Diagnostics, Inc. ("Accelerate Diagnostics,") (Nasdaq:AXDX), is an *in vitro* diagnostics company dedicated to providing solutions for the global challenge of antibiotic resistance and hospital acquired infections. The company's fully automated ID/AST system, Accelerate Pheno™, and direct from positive blood culture kit, Accelerate PhenoTest™ BC, utilize proprietary molecular and phenotypic detection technologies which have the potential to substantially reduce the time to antimicrobial susceptibility results while achieving high sensitivity and specificity. For more information about Accelerate Diagnostics, visit http://www.acceleratediagnostics.com.

Forward-Looking Statements

Certain of the statements made in this press release are forward looking, such as those, among others, about our projections as to when certain key business milestones may be achieved, including marketing authorization by the FDA of the Accelerate Pheno™ system and Accelerate PhenoTest™ BC kit for positive blood cultures, the commercial launch of the Accelerate Pheno™ system and Accelerate PhenoTest™ BC kit for positive blood cultures, the potential of our technology, the growth of the market, our estimates as to the size of our market opportunity and potential pricing, our competitive position and estimates of time reduction to results, and our future development plans and growth strategy. Actual results or developments may differ materially from those projected or implied in these forward-looking statements. Information about the risks and uncertainties faced by Accelerate Diagnostics is contained in the section captioned "Risk Factors" in the company's most recent Annual Report on Form 10-K, filed with the Securities and Exchange Commission on March 9, 2016. 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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Source: Accelerate Diagnostics, Inc.

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