Accelerate Diagnostics Receives FDA Marketing Authorization for the Accelerate Pheno™ System and Accelerate PhenoTest™ BC Kit

TUCSON, Ariz., Feb. 23, 2017 (GLOBE NEWSWIRE) -- Accelerate Diagnostics, Inc. (Accelerate) today announced that the U.S. Food and Drug Administration has granted the de novo request to market the Accelerate Pheno™ system and Accelerate PhenoTest™ BC kit for identification and antibiotic susceptibility testing of pathogens directly from positive blood culture samples. The blood culture kit is indicated for susceptibility testing of specific pathogenic bacteria commonly associated with bacteremia, the leading cause of sepsis.

The Centers for Disease Control and Prevention estimate at least 2 million people each year are infected with antibiotic resistant bacteria across the U.S. In addition, antibiotic resistance contributes to the morbidity and mortality of healthcare-associated infections (HAI) that kill an estimated 75,000 people annually.1

"The ability to provide not only rapid identification but also rapid phenotypic susceptibility ensures patients receive the most effective and appropriate therapy in a timely manner," said James Lewis, PharmD, Infectious Diseases Clinical Pharmacy Coordinator and Adjunct Associate Professor at Oregon Health and Science University and member of the CLSI Subcommittee on Antimicrobial Susceptibility Testing. "We know each hour of inadequate antibiotic therapy increases mortality and that excessive use of broad spectrum agents drives resistance. The faster we can tailor therapy, the better things are for the patient and the potential prevention of antibiotic resistance."

Culture based identification and susceptibility systems require time consuming manual procedures, resulting in laboratory processing time that often exceeds 48 hours. With the Accelerate PhenoTest™ BC kit, labs can reduce the turnaround time by testing directly from positive blood culture samples, producing results up to 40 hours faster than conventional methods.

The Accelerate PhenoTest™ BC kit is a multiplexed in vitro diagnostic test utilizing both qualitative nucleic acid fluorescence in situhybridization (FISH) identification and quantitative antimicrobial susceptibility testing methods intended for use with the Accelerate Pheno™ system. The blood culture kit is capable of simultaneous detection and identification of multiple microbial targets followed by susceptibility testing of the appropriate detected bacterial organisms using morphokinetic cellular analysis (MCA) of individual microbial cells and colonies under the challenge of antibiotics.

The Accelerate clinical study included more than 39,000 tests conducted on 1,850 samples across 13 trial sites and exceeded the requirements of the FDA for identification and antimicrobial susceptibility testing. The study showed overall sensitivity of 97.4% and specificity of 99.3% for identification. For susceptibility, overall essential and categorical agreement versus standard broth microdilution was 96.3% and 96.4% respectively.2

The Accelerate PhenoTest™ BC kit includes 140 assays for both identification and susceptibility testing, of which 116 were submitted to the FDA. The kit also includes what Accelerate refers to as a "definitive" monomicrobial test indicating when a patient's positive blood culture sample has only one targeted pathogen. In the Accelerate clinical trial the monomicrobial result had a 99.6% positive predictive value (PPV) when evaluated in combination with the Gram stain. The monomicrobial result, matched with a Gram stain, allows microbiologists to report results without additional laboratory workup.

"We are excited to offer microbiologists and treating physicians earlier intelligence about the infections they fight on a daily basis," said Lawrence Mehren, President and CEO of Accelerate Diagnostics, Inc. "Bringing this solution to market has been a culmination of years of effort. I could not be more proud of the Accelerate team, more grateful to our clinical trial partners, or appreciative of the FDA's guidance throughout this endeavor."

The FDA granted the de novo request from Accelerate to legally market the Accelerate Pheno™ system and Accelerate PhenoTest™ BC kit for in vitro diagnostic use. The de novo classification process provides a regulatory pathway intended to expedite FDA review of novel low-to-moderate risk devices for which no predicate device exists when special and general controls demonstrate reasonable assurance of safety and effectiveness.

Accelerate will discuss the de novo request granted by the FDA with investors and analysts on its preliminary earnings conference call scheduled for, Monday, February 27, 2017 at 4:15pm ET. A live audio webcast of the call will be accessible from the investor portal of the company's website at axdx.com/investors.

Visit axdx.com to get more information about the Accelerate Pheno™ system and Accelerate PhenoTest™ BC kit.

References:

1. Reports from the Centers for Disease Control and Prevention can be found at cdc.gov/hai/surveillance/ and cdc.gov/drugresistance/
2. Overall results are based on FDA/CLSI 2016 breakpoints - see product labeling for additional detail

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 healthcare-associated infections. The company's fully automated Accelerate Pheno™ system, and direct from positive blood culture Accelerate PhenoTest™ BC kit, leverage a suite of technologies to eliminate the lengthy culture and sample preparation steps required prior to testing. Using proprietary molecular identification methods and morphokinetic cellular analysis (MCA), the solution aims to reduce the time that clinicians must wait for quantitative antimicrobial susceptibility results necessary for optimal antibiotic selection, dosing, and infusion strategy, called minimum inhibitory concentrations, or MICs.

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, the potential of our products or 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 onMarch 9, 2016, and in any other reports that we file with the Securities and Exchange Commission from time to time. 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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