



FOR IMMEDIATE RELEASE

FDA Clears First One-Day Susceptibility Test for Diagnosis of Deadly Bacteria

-- KeyPath™ Test Can Determine Antibiotic Susceptibility for Staphylococcus aureus Infection Within Hours, Improving Treatment and Prevention --

Longmont, CO May 6, 2011 – MicroPhage, Inc., developers of quick easy-to-use diagnostic products for bacterial identification, antibiotic susceptibility and resistance testing, announced today it has received 510(k) clearance from the U.S. Food and Drug Administration to market its KeyPath™ MRSA/MSSA Blood Culture Test – BT, which returns same-day antibiotic susceptibility results for deadly *S. aureus* infections.

The test is unique because it not only enables doctors to identify a *S. aureus* infection; it also determines whether the strain is methicillin resistant (MRSA) or methicillin susceptible (MSSA), thus providing the physician with the means to determine an effective course of treatment.

“MRSA and other antibiotic-resistant ‘superbugs’ represent one of the greatest public health challenges of our century, and identifying those dangerous bacteria early is crucial in both treating patients and limiting the spread of the infection to others,” said Don Mooney, President and Chief Executive Officer at MicroPhage. “This test is a timely and a much-needed improvement to an important area of hospital and laboratory medicine.”

As many as half of all patients with *S. aureus* infections are initially prescribed inappropriate or sub-optimal antibiotics before traditional test methods return information about the bacteria’s antibiotic susceptibility. The KeyPath™ MRSA/MSSA Blood Culture Test – BT provides key diagnostic information that enables doctors to prescribe the most appropriate antibiotics for a patient’s infection up to two days sooner than is possible with current test methods.

The test is the first product developed using MicroPhage’s proprietary Bacteriophage Amplification Technology (BAT™) platform and meets stringent CLSI and FDA criteria. Unlike current test methods, which rely on lengthy culture procedures to isolate and characterize bacteria, BAT™ accelerates the process while exposing the bacteria to antibiotics, delivering true phenotypic antibiotic susceptibility results. The test requires only a few minutes of hands-on time and can be integrated into any laboratory immediately as no special instrumentation is required.

“The mortality rate for *S. aureus* bloodstream infections is in the range of 30 to 40 percent and patients are typically placed on a combination of antibiotics to fight the infection prior to obtaining the culture results. The information provided by this test will allow physicians to more rapidly optimize therapy, which is strongly correlated with better patient outcomes,” said Richard Proctor MD, Professor Emeritus at the University of Wisconsin Medical School. “Increasing rates of antibiotic resistance in most bacterial

pathogens makes antibiotic selection difficult. This test provides significant advantage over existing alternatives.”

The KeyPath™ MRSA/MSSA Blood Culture Test – BT was evaluated in a clinical study of 1,116 blood samples at four major U.S. hospital centers, including Duke University Medical Center, UMDNJ-Robert Wood Johnson Medical School, Northwestern University and Denver Health. The test was 98.9 percent accurate (178/180) for MRSA identification and 99.4 percent accurate (153/154) in determining MSSA within the organisms identified as *S. aureus*.

“Other methods, such as PCR, mass spectrometry and immunoassays have been introduced but only provide bacterial identification and, in some cases, markers for antibiotic resistance,” said Drew Smith, Ph.D., Chief Science Officer at MicroPhage. “However, these methods are affected by genetic mutations and other biological variables that can impact their accuracy. In contrast, the MicroPhage BAT™ platform provides a phenotypic result that directly assesses the organism’s response to an antibiotic. The platform can be extended to a broad range of bacterial pathogens and sample types thus enabling development of a long pipeline of clinically useful susceptibility tests and test panels.”

The MicroPhage product pipeline includes rapid single-pathogen and multi-pathogen diagnostic tests for simultaneous detection and determination of antibiotic susceptibility. The KeyPath™ MRSA/MSSA Blood Culture Test – BT has already achieved CE marking and commercialization efforts are under way in Europe.

About MicroPhage

Based in Longmont, Colorado, privately held MicroPhage, Inc. develops accelerated, easy-to-use diagnostic products for bacterial identification and antibiotic susceptibility/resistance testing. Using its proprietary Bacteriophage Amplification Test (BAT™) platform, the Company has developed patented processes that provide a platform for quick, easy-to-use, inexpensive diagnostic tests. The MicroPhage BAT™ test platform does not require any instrumentation and is simple to operate, enabling microbiology testing outside of traditional laboratory settings.

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