



MICROPHAGE

*News Release*

Contact: Ronald Trahan, APR, Ronald Trahan Associates Inc., 508-359-4005, x108

**MicroPhage concludes pivotal clinical study  
of world's first test designed to rapidly identify bacterial infections  
and antibiotic susceptibility without costly equipment**

**FDA submission for clearance to sell 'MicroPhage MRSA/MSSA  
Blood Culture Test' in U.S. is imminent; CE Mark already in place  
to sell test in Europe;  
first commercial shipment expected this month**

**Company setting new standard for fighting hospital acquired  
infections and reducing bacterial resistance**

LONGMONT, Colo., Jan. 12, 2010—[MicroPhage](#) announced today that it has **concluded a pivotal study** of the 'MicroPhage MRSA/MSSA Blood Culture Test', the first of its instrument-free, rapid tests based on patented *Bacteriophage Amplification* technology. Data from the pivotal study will support a U.S. Food and Drug Administration (FDA) **510(k) premarket notification**, which the Company will be submitting as soon as possible. **With CE Mark already in place, MicroPhage expects to begin commercial shipments this month.**

The Company's initial commercial product, which received regulatory clearance (CE Mark) this month to be sold in Europe, is designed to rapidly identify *Staphylococcus aureus* ("staph") bacteria as well as determine methicillin resistance (MRSA) or susceptibility (MSSA) in suspected cases of bacteremia—bacteria in the blood—in as little as five hours. Today's standard of care for determining these types of infections takes up to three days for test-results, which can result in ineffective treatment, bacterial resistance, and death.

"The conclusion of our pivotal study is a major milestone for MicroPhage," said CEO **Steve Lundy**. "Our initial commercial product, as well as the battery of additional tests we will offer based on our Bacteriophage Amplification **platform**, personifies a whole new paradigm for the effective *and* cost-effective testing of hospital patients."

"We are very excited about how the test has performed," said **Drew Smith, Ph.D.**, Vice President of Research and Development for MicroPhage, "With more than 1,200 samples tested across four major U.S. medical centers, the product seems to have met or passed all of our expectations." Full performance data from the product is expected later this year with scientific publications from the participating research centers.

The **MicroPhage MRSA/MSSA Blood Culture Test** requires no instrumentation and begins with two small reaction tubes for incubating blood culture specimens. After only five hours, the incubated samples are added to a dual dipstick-like detector, which looks much like a home pregnancy test. One part of the test will identify if the blood sample is infected with *S. aureus* bacteria and the other shows whether it is susceptible or resistant to methicillin-type antibiotics. Delivering this diagnostic information quickly will enable physicians to determine more effective

and precise antibiotics that could shorten hospital stays, lower health care costs and, ultimately, save lives. *S. aureus* bacteria typically has a mortality rate of >20 percent.

### **About MicroPhage's *Bacteriophage Amplification* Platform**

MicroPhage has adapted Bacteriophage Amplification, a natural biologic process, for identifying bacterial infections. *Bacteriophage* are harmless bacteria-specific viruses that multiply aggressively when exposed to target bacteria. In the detection process, reaction of the bacteriophage proteins on the MicroPhage detector indicates that the sample is positive for the bacteria. For susceptibility analysis, the organism in the sample is simultaneously challenged with an antibiotic. Because bacteriophage depend on host bacteria for amplification, any compound that kills or inhibits the microbe's growth will stop phage amplification. Only strains resistant to the antibiotic allow this amplification and yield a positive signal on the second detector strip on the test, indicating an MRSA infection. The platform allows for rapid, high-performing tests without the need for expensive equipment or dedicated time of laboratory staff.

### **About Staph Infections**

*Staphylococci* are frequently implicated in bloodstream infections (BSIs) with high morbidity and mortality. In a multinational study<sup>1</sup>, 36 percent of bloodstream isolates were staphylococci, 61 percent of which were *Staphylococcus aureus*. In a prospective cohort of patients with hospital-acquired BSIs in the United States, *S. aureus* was a primary cause, accounting for 20 percent of cases. The incidence of *S. aureus* bacteremia has increased significantly over the past decade, largely due to the increasing use of intravascular catheters and invasive devices. There has also been a significant rise in rates of *methicillin-resistant S. aureus* (MRSA). Almost 60 percent of *S. aureus* bacteremia in the U.S. is now caused by these resistant strains. Despite advances in medical therapy and diagnostic procedures, *S. aureus* bacteremia is often associated with serious complications, with a mortality rate that exceeds 20 percent, especially if appropriate therapy is not administered rapidly. A rapid and reliable test for this diagnosis would allow clinicians to optimize diagnostic and therapeutic decisions. Antibiotic therapy could be adjusted early, leading to better health outcomes for patients along with lower pharmacy and hospitalization costs.

### **About MicroPhage, Inc.**

Based in Longmont, Colorado, privately held MicroPhage, Inc. is working to be a global leader in developing rapid, easy-to-use diagnostic products for bacterial identification and antibiotic susceptibility/resistance testing. Using its proprietary *Bacteriophage Amplification* platform, the Company has developed a patented process that is a product platform for rapid, easy-to-use, inexpensive diagnostic and screening tests. The technology platform resembles a home pregnancy test with twin, rapid detectors. The platform does not require any instrumentation and is simple to operate, enabling microbiology testing outside of traditional laboratory settings.

<sup>1</sup> Diekema DJ, Schmitz FJ, Pfaller MA, Bell J, Smayevsky J, Beach M, Jones RN, and the SENTRY Participants Group. Survey of infections due to *Staphylococcus* species: frequency of occurrence and antimicrobial susceptibility of isolates collected in the United States, Canada, Latin America, Europe, and the Western Pacific region for the SENTRY antimicrobial surveillance program, 1997–1999. *Clin Infect Dis* 2001;32:S114–S132

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