



**MICROPHAGE**

## News Release

### FOR IMMEDIATE RELEASE

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

### **MicroPhage obtains CE Mark to sell world's first rapid MRSA/MSSA test in Europe**

### **First test of platform designed to rapidly identify MRSA and MSSA infections without costly equipment**

[Company seeks to establish new standard for fighting hospital-acquired infections/reducing bacterial resistance](#)

### **MicroPhage expects to file for FDA clearance within weeks**

LONGMONT, Colo., Dec. 7, 2009-[MicroPhage](#) announced today that it has obtained its **CE Mark** to market in Europe the first of its instrument-free, rapid tests based on its patented *Bacteriophage Amplification* technology. The Company's initial commercial product 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 **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.

"Our initial product, as well as the family of tests we intend to offer based on our Bacteriophage Amplification platform, represents a new paradigm for the effective, cost-effective testing of hospital patients," said MicroPhage CEO, **Steve Lundy**. "Hospital-acquired infections (HAIs) are a

colossal problem, killing more than 15 million<sup>1</sup> persons worldwide each year and costing the U.S. \$29 billion<sup>2</sup> in unnecessary health care expense. We believe that our initial test will be extremely well received in Europe as well as in the U.S.

"Our first commercial product establishes a new standard for clinicians in *S. aureus* identification and antibiotic susceptibility testing, and it is designed to complement the demands of hospitals and laboratories of all sizes," Lundy added. "We are developing additional tests, including rapid tests for screening of high-risk patients, skin and soft tissue infections, as well as respiratory infections for *S. aureus* and other bacteria of clinical interest."

In August, MicroPhage announced the start of a multi-site clinical trial to support its U.S. Food and Drug Administration (FDA) premarket notification 510(k) submission, which is expected to be filed shortly. The clinical study involves four major medical centers throughout the U.S. and is expected to test more than 1,000 specimens with the **MicroPhage MRSA/MSSA Blood Culture Test** to demonstrate its safety and performance. The MicroPhage test is being compared to a battery of laboratory "gold standard" tests to determine its performance.

#### **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>3</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.

1 The World Health Report - 2004 Annex Table 2

2 The International Federation of Infection Control (THEIFIC)

3 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

#####