AmpliPhi Biosciences Announces Presentation of Positive Clinical Data From its Expanded Access Program for Serious S. aureus Infections at IDWeek 2018 Conference

13 patients with serious and life-threatening S. aureus infections were treated with AB-SA01 at the Westmead Hospital in Sydney under AmpliPhi's expanded access program

Patients suffered from severe S. aureus bacteremia and sepsis, including infective endocarditis and prosthetic valve endocarditis

83% (10 out of 12) patients in the modified intent-to-treat (mITT) population achieved treatment success at the end of therapy as reported by treating physicians

Bacteriophage treatment was well tolerated, with no adverse events attributable to the therapy

"Adjunctive bacteriophage therapy for severe Staphylococcal sepsis"

SAN DIEGO--(<u>BUSINESS WIRE</u>)--AmpliPhi Biosciences Corporation (NYSE American:APHB), a clinical-stage biotechnology company focused on precisely targeted bacteriophage therapeutics for antibiotic-resistant infections, today announced the presentation of clinical case series data from the company's ongoing expanded access program for its investigational bacteriophage therapeutic, AB-SA01 targeting *Staphylococcus aureus* (*S. aureus*), at the IDWeek 2018 conference in San Francisco.

Prof. Jonathan Iredell, Senior Staff Infectious Diseases Physician at the Westmead Hospital in Sydney, Director of Centre for Infectious Diseases and Microbiology at the Westmead Institute of Medical Research and Professor of Medicine and Microbiology at the University of Sydney, gave a presentation "Adjunctive bacteriophage therapy for severe Staphylococcal sepsis," including data on 13 patients suffering from severe *S. aureus* infections, who were treated with AB-SA01 as an adjunct to antibiotics at the Westmead Hospital in 2017-2018. The potential treatment of *S. aureus* bacteremia with AB-SA01 was also the subject of the Company's recent Type B meeting with the FDA. The treatment was conducted under emergency protocols per the Australian Therapeutic Goods Administration's (TGA) Special Access Scheme (SAS).

Highlights from the presentation include the following:

- 13 patients treated with AB-SA01 had severe *S. aureus*sepsis and/or bacteremia. The patients had not responded to prior conventional antibiotic therapy and were eligible for treatment with AB-SA01 under the Australian TGA SAS Category A, which allows therapy for a patient who is "seriously ill with a condition from which death is reasonably likely to occur within a matter of months, or from which premature death is reasonably likely to occur in the absence of early treatment."
- 10 of the patients also suffered from infective endocarditis (infection of the endocardium, the inner lining of the heart chambers and heart valves), and 5 of these patients had prosthetic valve endocarditis, which can be particularly challenging to treat with antibiotics due to formation of bacterial biofilm.
- Approximately 290 doses of AB-SA01 were administered intravenously and were well tolerated with no
 adverse events attributable to AB-SA01.
- 83% of patients (10 out of 12) in the mITT population achieved treatment success at the end of therapy. Treatment success, as determined by the treating physician, was defined as a complete resolution or significant improvement of baseline signs and symptoms.
- Initial gene expression data indicate that bacteriophage treatment may downregulate pro-inflammatory genes and upregulate anti-inflammatory genes, which could be important for treatment of patients with sepsis to prevent septic shock and for patients with endocarditis to prevent destruction of heart tissue.

About AmpliPhi Biosciences

AmpliPhi Biosciences Corporation is a clinical-stage biotechnology company focused on treating antibioticresistant infections using its proprietary bacteriophage-based technology. AmpliPhi's lead clinical stage product candidates, AB-SA01 and AB-PA01, target multidrug-resistant *Staphylococcus aureus* and *Pseudomonas aeruginosa*, which are included on the WHO's 2017 Priority Pathogens List. Phage therapeutics are uniquely positioned to address the threat of antibiotic-resistance as they can be precisely targeted to kill select bacteria, have a differentiated mechanism of action, can penetrate and disrupt biofilms (a common bacterial defense mechanism against antibiotics), are potentially synergistic with antibiotics and have been shown to restore antibiotic sensitivity to drug-resistant bacteria. For more information visit <u>www.ampliphibio.com</u>.

About Bacteriophages

Bacteriophages, or more simply "phages," are the natural predators of bacteria and are thought to be the most abundant life form on earth. Phages have evolved an incredible diversity of strains that typically prey upon just a few closely related strains or species of bacteria, enabling phage therapies to precisely target pathogenic bacteria while sparing the beneficial microbiota. Phages can infect and kill bacteria, whether they are antibioticresistant or not, and even when they have formed protective biofilms.

Forward Looking Statements

Statements in this press release that are not statements of historical fact are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Such forward-looking statements include, without limitation, statements regarding: the potential benefits of phage therapy; and the potential use of bacteriophages to treat bacterial infections, including infections that do not respond to antibiotics or are associated with biofilms. Words such as "believe," "anticipate," "plan," "expect," "intend," "will," "may," "goal," "potential" and similar expressions are intended to identify forward-looking statements, though not all forward-looking statements necessarily contain these identifying words. Among the factors that could cause actual results to differ materially from those indicated in these forward-looking statements are risks and uncertainties associated with bacteriophage product candidate development, both generally and specifically through expanded access regulations, AmpliPhi's financial condition, and other risks and uncertainties described in AmpliPhi's Annual Report on Form 10-K for the year ended December 31, 2017, as filed with the Securities and Exchange Commission (SEC), and AmpliPhi's subsequent filings with the SEC. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this press release. All forward-looking statements are qualified in their entirety by this cautionary statement, and AmpliPhi undertakes no obligation to revise or update any forward-looking statements to reflect events or circumstances after the date of this press release.

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https://investor.armatapharma.com/2018-10-08-AmpliPhi-Biosciences-Announces-Presentation-of-Positive-Clinical-Data-From-its-Expanded-Access-Program-for-Serious-S-aureus-Infections-at-IDWeek-2018-Conference