

AmpliPhi Biosciences Announces Updated Positive Clinical Results for its Expanded Access Program

*21 patients at 7 hospitals, with serious or life-threatening infections not responding to antibiotics, have now been treated with AB-SA01 (targeting *S. aureus*) or AB-PA01 (targeting *P. aeruginosa*) under AmpliPhi's expanded access program*

Over 1,000 doses of bacteriophage product candidates, AB-SA01 or AB-PA01, have been administered as part of the expanded access program since mid-2017 and have been generally well tolerated, with no serious adverse events attributable to bacteriophage treatment

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SAN DIEGO--([BUSINESS WIRE](#))--AmpliPhi Biosciences Corporation (NYSE American: APHB), a clinical-stage biotechnology company focused on precisely targeted bacteriophage therapeutics for antibiotic-resistant infections, today announced updated topline clinical results for its ongoing single-patient expanded access program. 84% of patients achieved treatment success (physician's assessment) at the end of therapy, defined as complete resolution or significant improvement of baseline signs and symptoms.

AmpliPhi has now provided its investigational bacteriophage therapeutics for a total of 21 patients, at 7 hospitals, with serious or life-threatening infections not responding to antibiotic therapy. These patients were treated with AB-SA01 or AB-PA01 under single-patient expanded access programs in the U.S. (Emergency INDs per the U.S. Food and Drug Administration) or Australia (Special Access Scheme per the Australian Therapeutic Goods Administration). The following analysis updates the data previously announced by the company on January 3, 2018:

- 15 patients with serious *S. aureus* infections were treated with AB-SA01 and 6 patients with serious *P. aeruginosa* infections were treated with AB-PA01.
- Infections in the treated patients included bacteremia, native and prosthetic valve endocarditis, recurrent pneumonia, ventilator-associated pneumonia, prosthetic joint infection, ventricular assist device infection, and others.
- Over 1,000 bacteriophage doses were administered as part of the expanded access program including:
 - 400+ doses of AB-SA01, including 300+ doses administered intravenously. Treatment was well-tolerated in all patients with no treatment related serious adverse events (SAEs).
 - 600+ doses of AB-PA01, including 400+ doses administered intravenously. Treatment was well-tolerated in five patients. One patient discontinued treatment due to Grade 1 and 2 adverse events, which resolved within 18 hours. There were no treatment-related SAEs.
- 84% (16 out of 19) of patients in the modified intent-to-treat population (mITT) 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. mITT population was defined as all patients who met the criteria for clinical diagnosis, whose bacterial isolate was susceptible to phage and who received at least one dose of phage.

“The encouraging results from AmpliPhi’s expanded access program support the view that phage therapeutics can be safely administered and provide anecdotal evidence of their efficacy, which we hope to soon demonstrate in randomized, controlled clinical trials,” said Dr. 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. “I look forward to helping bring this potentially important new modality to seriously ill patients, including those in whom usual treatment options are commonly inadequate.”

About AmpliPhi Biosciences

AmpliPhi Biosciences Corporation is a clinical-stage biotechnology company focused on treating antibiotic-resistant 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 www.ampliphio.com.

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 antibiotic-resistant 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; the potential use of bacteriophages to treat bacterial infections, including infections that do not respond to antibiotics or are associated with biofilms and the potential success of AmpliPhi’s planned clinical trials. 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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