Investor Relations

AmpliPhi Biosciences Announces Positive FDA Feedback for its Clinical Stage Bacteriophage Product Candidate AB-PA01 Targeting Pseudomonas Aeruginosa Infections

The FDA is in general agreement with the design of two proposed randomized clinical trials of AB-PA01, hospital-acquired and ventilator-associated pneumonia (HAP/VAP) due to P. aeruginosa and for P. aeruginosa bacteremia, and no additional preclinical or clinical data are required to proceed with both trials

Based on the positive FDA feedback, AmpliPhi intends to seek non-dilutive financing and explore other opportunities to conduct these clinical trials

"We are delighted with the FDA's response to our development plans for AB-PA01, AmpliPhi's bacteriophage product candidate targeting Pseudomonas aeruginosa infections, and the FDA's concurrence on the proposed design of two randomized controlled clinical trials, in hospital-acquired and ventilator-associated pneumonia and P. aeruginosa bacteremia"

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 that the company has received positive feedback, via written response, from the U.S. Food and Drug Administration (FDA) regarding its development plans for AB-PA01, without the need for a Type B Pre-IND meeting.

"We are delighted with the FDA's response to our development plans for AB-PA01, AmpliPhi's bacteriophage product candidate targeting *Pseudomonas aeruginosa* infections, and the FDA's concurrence on the proposed design of two randomized controlled clinical trials, in hospital-acquired and ventilator-associated pneumonia and *P. aeruginosa* bacteremia," said Paul C. Grint, M.D., CEO of AmpliPhi Biosciences. "Resistant *P. aeruginosa* is designated as 'Priority 1: Critical' pathogen on the World Health Organization's Priority Pathogens List and as 'Serious Threat' by the U.S. Centers for Disease Control and Prevention."

"Additionally, I am strongly encouraged to see the FDA's dedication to addressing the challenges of antimicrobial resistance and promoting the development of new products, including bacteriophage therapeutics, as stated by the FDA's Commissioner, Scott Gottlieb, at the unveiling of the FDA's 2019 Strategic Approach for Combating AMR on September 14, 2018."

AmpliPhi's engagement with the FDA included an update on the company's ongoing Expanded Access Program, as well as the proposed design for two randomized, controlled clinical trials with AB-PA01, the company's clinical candidate targeting *P. aeruginosa*. The FDA was in general agreement with the proposed clinical trial designs and, based on the current FDA feedback, no additional clinical or nonclinical data are required to proceed with the following two proposed randomized clinical trials:

- A Phase 1/2 randomized, controlled clinical trial to evaluate the safety and efficacy of AB-PA01, administered intravenously with the best available antibiotic therapy, compared to placebo plus best available antibiotic therapy, in approximately 100 patients with hospital-acquired and ventilator-associated pneumonia (HAP/VAP) due to *Pseudomonas aeruginosa*
- A Phase 1/2 randomized, controlled clinical trial to evaluate the safety and efficacy of AB-PA01, administered intravenously with the best available antibiotic therapy, compared to placebo plus best available antibiotic therapy, in approximately 100 patients with *P. aeruginosa* bacteremia

"*Pseudomonas aeruginosa* is not only a challenging infection to treat, but one that represents a serious threat to the cystic fibrosis community as well as to lung transplant patients," said Saima Aslam, M.D., Director, Solid Organ Transplant Infectious Diseases, University of California San Diego School of Medicine. "Having been involved in cases that have used emergency INDs to treat patients with investigational bacteriophage therapy, I welcome today's news, as it has the potential to bring more widespread use of this treatment to the critically ill patients who could benefit from it."

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. AmpliPhi received regulatory guidance for the development of its bacteriophage therapy and intends to initiate the first randomized clinical trial for AB-SA01 in early 2019. 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.ampliphibio.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; the potential acceptance of phage therapy as a treatment within the medical and scientific communities; AmpliPhi's plan to seek non-dilutive financing and explore other opportunities to conduct clinical trials of AB-PA01; AmpliPhi's ability to successfully initiate or complete its proposed clinical trials and AmpliPhi's ability to obtain regulatory approval for its product candidates. 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.

CONTACT:

At the Company:
AmpliPhi Biosciences
Steve Martin, 858-800-2492
ir@ampliphibio.com
or
Investor Relations:
Westwicke Partners
Robert H. Uhl, 858-356-5932
robert.uhl@westwicke.com
