Investor Relations

AmpliPhi Biosciences Announces Positive FDA Feedback for its Clinical Stage Bacteriophage Product Candidate AB-SA01

FDA is in general agreement with the design of two proposed randomized clinical trials of AB-SA01, for Staphylococcus aureus bacteremia and prosthetic joint infections, and no additional preclinical or clinical data are required to proceed with both trials

AmpliPhi expects to initiate one of these clinical trials in early 2019

AmpliPhi continues to investigate if AB-SA01 may be eligible for approval under the Limited Population pathway (LPAD pathway), which is intended to facilitate development of therapeutics to treat serious or life-threatening infections in a limited population of patients with unmet need

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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 that the company had a Type B Pre-IND meeting with the U.S. Food and Drug Administration (FDA) and has now received the meeting minutes. Based on the FDA's feedback, AmpliPhi currently plans to initiate the first randomized clinical trial of its AB-SA01 bacteriophage therapy product candidate in early 2019. The clinical trial is expected to enroll approximately 100 patients. AmpliPhi's wholly-owned GMP-certified manufacturing facility has the capacity to produce the company's proprietary bacteriophage therapeutics for the planned clinical trials, through an anticipated BLA filing and potential approval.

"I'm excited by the positive feedback that we have received from our August meeting with the FDA, which is the result of our clinical, regulatory and manufacturing accomplishments since we updated our strategy in mid-2017," said Paul C. Grint, M.D., CEO of AmpliPhi Biosciences. "We have provided our investigational bacteriophage therapeutic candidates to over 20 seriously ill patients under compassionate use emergency protocols and collected clinical and microbiological data to inform the path for further development. We summarized these data, the subject of another press release issued earlier today, in the briefing package to the FDA and received concurrence on the proposed design of two randomized controlled clinical trials. These two trials, in bacteremia and prosthetic joint infections, would be the first trials we are aware of for an intravenously administered bacteriophage therapy."

The Type B Pre-IND meeting included discussion of the results from AmpliPhi's ongoing Expanded Access Program and the proposed design for two randomized, controlled clinical trials with AB-SA01, the company's clinical candidate targeting *S. aureus*, that were developed based on input from infectious disease physician thought leaders.

The FDA was in general agreement with the proposed clinical trial designs:

- A Phase 1/2 randomized, controlled clinical trial to evaluate the safety and efficacy of AB-SA01, administered intravenously with the best available antibiotic therapy, compared to placebo plus best available antibiotic therapy, in approximately 100 patients with *S. aureus* bacteremia.
- A Phase 1/2 randomized, controlled clinical trial to evaluate the safety and efficacy of AB-SA01, administered by intra-articular injection and then intravenously with the best available antibiotic therapy, compared to placebo plus the best available antibiotic therapy, in approximately 100 patients with a hip or knee prosthetic joint infection due to *S. aureus* as an adjunct to surgical treatment.

Importantly, based on the current FDA feedback, no additional clinical or nonclinical data are required to proceed with the two proposed randomized clinical trials. Furthermore, AmpliPhi continues to investigate if AB-SA01 may be eligible for Fast Track Designation and for approval under the Limited Population pathway (LPAD pathway), which is intended to facilitate development of therapeutics to treat serious or life-threatening infections in a limited population of patients with unmet need. Products eligible for approval under the LPAD pathway may follow streamlined approaches for clinical development, which may involve smaller, shorter, or fewer clinical trials to help reduce the overall product development timeline.

"I welcome today's announcements from AmpliPhi Biosciences, which should hasten the development of bacteriophage therapeutics to address the increasingly urgent need of antibiotic-resistant bacterial infections," said Robert T. Schooley, M.D., Professor in the infectious disease division at the University of California, San Diego (UCSD) and co-founder of North America's first Center for Innovative Phage Applications and Therapeutics at UCSD School of Medicine. "I am pleased to see that, by its actions, the FDA supports the promise of this treatment approach. I also note that phage therapeutics will be given a plenary session at the upcoming IDWeek 2018, which further points to the growing acceptance by the medical and scientific communities of the potential of this technology to treat critically ill patients."

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 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 ability to successfully 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.

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