Investor Relations

AmpliPhi Biosciences Announces a New Strategic Emphasis on Personalized Therapies for Serious or Life-Threatening Antibiotic-Resistant Infections

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SAN DIEGO--(BUSINESS WIRE)--AmpliPhi Biosciences Corporation (NYSE MKT: APHB), a leader in the field of bacteriophage technology, announces a new strategic emphasis on precisely targeted and personalized medicines designed to address the surging global threat posed by bacteria that have become resistant to antibiotics. Under existing compassionate-use guidelines, AmpliPhi expects to provide personalized phage therapies to patients suffering from severe, multidrug-resistant (MDR) infections who have failed prior therapies. In addition to offering hope to patients and families in dire need, the clinical data from these compassionate-use cases are expected to support the potential validation of the clinical utility of phage therapy and inform discussions with the U.S. Food and Drug Administration (FDA) on defining a potential path to market approval.

Bacteriophages are thought to be the most abundant and diverse life form on Earth. Members of this family of viruses have evolved to fulfill one mission: to invade bacteria in order to replicate in a process that destroys the bacterial host. These natural-born bacteria killers terminate their prey differently than conventional antibiotic drugs, making them ideal natural elements in a new class of therapeutics with the potential to safely and precisely destroy even the most highly antibiotic-resistant bacteria. Bacteriophages also have shown synergistic effects when combined with traditional antibiotic therapies as demonstrated in both clinical and preclinical studies.

In the official minutes from a recent telephonic Type B meeting with the FDA and in the context of discussing personalized therapies, the FDA “stated that the clinical safety and effectiveness data collected during development, including from emergency case studies, could inform future discussions for clinical development and, ultimately, the regulatory pathway to approval.” The FDA also “acknowledged that phage therapy is an exciting approach to treatment of multidrug-resistant organisms and expressed a commitment to addressing the unique regulatory challenges that might arise during product development.”

Personalized phage therapies will initially be made available in Australia, where AmpliPhi plans to collaborate with leading hospitals and key opinion leaders to identify and select eligible patients. This new emphasis on personalized medicine builds upon AmpliPhi’s prior successes using tailored bacteriophage therapies under emergency INDs to treat individual patients battling life-threatening, MDR bacterial pathogens who had exhausted their treatment options.

As previously reported, in March 2016 AmpliPhi collaborated with several academic institutions and a U.S. Navy laboratory to produce a personalized bacteriophage therapy that successfully treated a critically ill, comatose patient with an MDR *Acinetobacter baumannii* (*A. baumannii)*infection. Shortly after phage therapy was initiated, the patient emerged from the coma and continued to improve under an ongoing combination of phage and antibiotic therapies until the infection was cleared. To date, the infection has not returned.

Additionally, AmpliPhi’s wholly owned subsidiary, Special Phage Services, was instrumental in developing a personalized phage therapy that eliminated an antibiotic-resistant *Pseudomonas aeruginosa* (*P. aeruginosa*) infection in the bladder of a female cancer patient. The results of this case were published in a manuscript in the *Journal of Medical Microbiology* in 2011.

Dr. Jonathan Iredell, Professor of Medicine and Microbiology at the University of Sydney and Westmead Institute of Medical Research, Director, Infectious Diseases, Westmead Hospital, who treated the bladder cancer patient and is the corresponding author of the manuscript, said, “Bacteriophage therapy holds high promise for treating serious, resistant bacterial infections and for providing much-needed new therapeutic options for patients. I believe this therapeutic modality needs to be rapidly explored in a clinical setting to better understand its potential and make it available to patients.”

Starting with samples taken from infected patients, AmpliPhi expects to be able to screen its bacteriophage libraries to craft patient-tailored therapies. Treatment of MDR *Staphylococcus aureus* (*S. aureus*) or *P. aeruginosa* infections could start within as little as a few days of receiving the infected patient samples since AmpliPhi already has broadly active, clinical-trial ready phage mixtures against these more common pathogens. For other pathogens, the Company expects in many cases to be able to develop personalized bacteriophage therapies within approximately two weeks of receiving the infected patient samples, as demonstrated in the recent *A. baumannii* infection case.

AmpliPhi is also seeking opportunities to advance its chronic rhinosinusitis (CRS) program (positioned for a Phase 2 trial) and preclinical cystic fibrosis (CF) program through partnerships and non-dilutive funding.

Financial Update

AmpliPhi had cash and cash equivalents of $2.2 million as of March 31, 2017, and has made operational changes that are expected to reduce its cash expenditures in 2017 and support its strategic emphasis on precisely targeted personalized bacteriophage therapies. The Company has filed its Australian tax return and now expects the receipt of a $1.8 million tax incentive payment early in the third quarter of 2017, subject to review by the Australian tax authority.

About Antibiotic Resistance

Decades of misuse and over-use of antibiotics has led to the rise of multidrug-resistant and pan-resistant bacteria, commonly known as “superbugs.” These superbugs threaten to render existing antibiotic therapies useless, potentially thrusting the world into a “post-antibiotic” era where common infections may be life threatening. Hospitals regularly expose vulnerable patients to pathogenic bacteria. According to the World Health Organization, each year hundreds of millions of patients worldwide suffer from infections acquired in a hospital setting. The Centers for Disease Control and Prevention (CDC) estimates that drug-resistant bacteria cause at least 2 million infections per year in the U.S. alone, resulting in over 23,000 deaths and many more people die from other conditions that are complicated by antibiotic-resistant infections. The 2016 O’Neill Report commissioned by the UK government projects that the failure to respond to the threat of antibiotic resistance and the rise of superbugs could lead to an estimated 10 million deaths per year from antibiotic-resistant infections worldwide by 2050, with an accumulated global cost of $100 trillion and a 3.5% reduction in global GDP.

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. Over eons, phages have evolved an incredible diversity of specialist strains that typically prey upon just one strain 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.

About AmpliPhi Biosciences

AmpliPhi Biosciences Corporation is a biotechnology company pioneering the development and commercialization of therapies for antibiotic-resistant infections using bacteriophage-based technology. In May 2017, AmpliPhi announced a new strategic emphasis on developing precisely targeted and personalized bacteriophage therapies for patients with serious or life-threatening antibiotic-resistant infections. AmpliPhi has reported results from two Phase 1 clinical trials of AB-SA01, one for the treatment of *S. aureus* in chronic rhinosinusitis patients (safety and preliminary efficacy) and one to evaluate the safety of AB-SA01 when administered topically to the intact skin of healthy adults. For more information, visit www.ampliphibio.com.

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 about the potential use of bacteriophages to treat bacterial infections, the Company’s ability to develop targeted and personalized medicines for patients with serious or life-threatening antibiotic-resistant infections, the Company’s ability to advance its research and development programs through partnerships and non-dilutive funding, the regulatory pathway for approval of phage therapies, the potential benefits of phage therapies, the Company’s cash runway and expected receipt of cash payments. 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 AmpliPhi’s business and financial condition and the other risks and uncertainties described in AmpliPhi’s Annual Report on Form 10-K for the year ended December 31, 2016, as filed with the SEC, and other filings with the SEC, including our Current Report on Form 8-K filed with the SEC on May 1, 2017. 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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