Investor Relations

AmpliPhi Biosciences Provides Corporate and Strategic Update

Under single-patient expanded access program, seven patients with serious and life-threatening infections, not responding to antibiotics, were treated with AB-SA01 or AB-PA01 in 2017. Company plans to present topline results in early 2018

Company expects to continue its expanded access clinical strategy in 2018, review data with FDA in mid-2018 and initiate Phase 2 or registrational clinical trial as early as the second half of 2018

Company is pursuing various approaches to fund Phase 2 clinical development and has engaged Ladenburg Thalmann & Co. Inc. to review strategic alternatives

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SAN DIEGO--(BUSINESS WIRE)--AmpliPhi Biosciences Corporation (NYSE American: APHB), a clinical-stage biotechnology company focused on the development of therapies for antibiotic-resistant infections using bacteriophage technology, today announced its progress in 2017 and near-term strategic goals and initiatives.

2017 Corporate Highlights

- In April, AmpliPhi received positive feedback from a U.S. Food and Drug Administration (FDA) Type B meeting in which the FDA “acknowledged that phage therapy is an exciting approach to treatment of multi-drug resistant organisms and expressed a commitment to addressing the unique regulatory challenges that might arise during product development.” The FDA also 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.”
- In August, AmpliPhi announced the first-in-human administration of its therapeutic candidate AB-PA01 targeting *Pseudomonas aeruginosa* (*P. aeruginosa*) under an Emergency IND allowed by the FDA. AmpliPhi provided AB-PA01 for a patient suffering from a life-threatening multidrug-resistant *P. aeruginosa* lung infection. Multiple doses of AB-PA01 were administered intravenously and by inhalation through a nebulizer and were well tolerated.
- In September, AmpliPhi announced the first-in-human intravenous administration of its therapeutic candidate AB-SA01 targeting *Staphylococcus aureus* (*S. aureus*) under the Special Access Scheme of the Australian Therapeutic Goods Administration. AmpliPhi provided AB-SA01 for a patient suffering from a life-threatening *S. aureus* endocarditis. AB-SA01 was administered intravenously over a two week duration and was well tolerated.
- A total of seven patients, suffering from serious and life-threatening infections who were not responding to antibiotic therapy, have been treated with AB-SA01 or AB-PA01 in 2017.
- Raised $9.4 million in net proceeds from an equity securities offering in May, and received a $2.0 million Research and Development Tax Incentive cash rebate in September from the Australian Tax Office based on the Company’s R&D spending in Australia during 2016.
- Continued to raise awareness of the Company’s bacteriophage development programs through presentations and participation in various scientific and medical meetings, including: 2017 Australian Society of Otolaryngology Head and Neck Surgery Meeting in March, Solutions for Drug-Resistant Infections Meeting in Brisbane in April, and “Bacteriophage Therapy: Scientific and Regulatory Issues” workshop sponsored by the FDA and the National Institutes of Health in July.
- In December, the Company engaged Ladenburg Thalmann & Co. Inc. to assist the Company in exploring strategic alternatives in an effort to maximize shareholder value. The Company has not set a timetable for completion of this exploratory process and cannot provide any assurances that the process will result in the consummation of a strategic transaction of any kind, or that the Company will not abandon the process. The Company does not intend to discuss or disclose further developments during this process unless and until its board of directors has approved a specific action or the Company otherwise determines that further disclosure is appropriate.

Potential Milestones and Initiatives for the First Half of 2018

- In early 2018, the Company plans to present topline results from the treatment of seven patients with serious and life-threatening infections, not responding to antibiotics, completed under the Company’s single-patient expanded access program in 2017.
- The Company intends to continue its expanded access clinical strategy in the first half of 2018, present data from approximately 25 expanded access clinical cases to the FDA in mid-2018 and initiate a Phase 2 or registrational clinical trial as early as the second half of 2018.
- The Company will present an overview and update of its current business activities at the 9th Annual Biotech Showcase Conference on January 8, 2018 at 9:30 a.m. PT being held in San Francisco.

“AmpliPhi has made tremendous progress throughout 2017,” said Paul C. Grint, M.D., CEO of AmpliPhi Biosciences. “To date, under the expanded access program, we have dosed seven patients in dire need, who were suffering from serious and life-threatening infections and were not responding to antibiotic therapies. We look forward to presenting topline results in early 2018. We have set a goal of dosing approximately 20 additional patients during the first half of 2018. We continue the dialogue with the FDA and key thought leaders in the infectious disease community regarding design of Phase 2 and registrational clinical studies of our bacteriophage therapies.”

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 product candidates 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.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 regarding: AmpliPhi’s plan to present topline results in early 2018 for the seven patients dosed with AB-SA01 or AB-PA01; AmpliPhi’s plan to dose approximately 20 additional patients with its bacteriophage therapies during the first half of 2018; AmpliPhi’s plan to present data from approximately 25 expanded access clinical cases to the FDA in mid-2018 and potentially initiate a Phase 2 or registrational clinical trial as early as the second half of 2018; and 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 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 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:

AmpliPhi Biosciences
Matthew Dansey, (858) 800-4869
md@ampliphibio.com
or
Investor Relations:
Westwicke Partners
Robert H. Uhl, (858) 356-5932
robert.uhl@westwicke.com
or
Media:
Russo Partners, LLC
David Schull or Maggie Beller
(212) 845-4271
David.Schull@RussoPartnersLLC.com
Maggie.Beller@RussoPartnersLLC.com
