Investor Relations

Armata Pharmaceuticals Announces the Completion of Enrollment of its Phase 1b/2a diSArm Study Evaluating Intravenous AP-SA02 as a Potential Treatment for Staphylococcus aureus Bacteremia

Topline data anticipated in Q1 2025 to support potential initiation of a pivotal bacteremiaefficacy trial in 2025

LOS ANGELES, Nov. 12, 2024 /PRNewswire/ -- Armata Pharmaceuticals, Inc. (NYSE American: ARMP) ("Armata" or the "Company"), a clinical-stage biotechnology company focused on pathogen-specific bacteriophage therapeutics for antibiotic-resistant and difficult-to-treat bacterial infections, today announced that it has achieved full enrollment (n=50) of its Phase 1b/2a diSArm study of intravenous AP-SA02 as a potential treatment for *Staphylococcus aureus* (*S. aureus*) bacteremia. Armata anticipates topline data from the diSArm study in the first quarter of 2025.

"The completion of enrollment of our diSArm study is a significant milestone in the development of AP-SA02, moving us one step closer to introducing an effective new treatment option to patients suffering from *S. aureus* bacteremia, a very serious bloodstream infection with high rates of morbidity and mortality and evolving resistance to most antibiotics," stated Dr. Deborah Birx, Chief Executive Officer of Armata. "With enrollment now complete, we are on track to report topline data in the first quarter of 2025 that, if positive, will support initiation of a pivotal bacteremia efficacy study later in the year. I am very pleased with the efficiency with which we continue to advance this important program."

During the Phase 2a portion of diSArm, Armata focused on evaluating clinical safety of higher intravenous doses of AP-SA02 and accelerating enrollment to arrive at topline data expeditiously. The manufacture of highly purified phages using Armata's proprietary methods enabled dose escalation to 5E10 PFU every six hours (2E11 PFU every 24 hours) for five days without clinically significant adverse events. In parallel with dose escalation, the evolution of two distinct blinded subsets of subjects receiving phage has been observed. One subset, comprising approximately half of the treated group, has evidence of persistence of detectable phage in the blood providing early evidence of *in vivo* phage amplification and resultant release of phage progeny. The Company anticipates topline data from the diSArm study in the first quarter of 2025 where it can explore the two aforementioned subsets in an unblinded manner. Topline results are also expected to inform the optimal dose of AP-SA02 to be evaluated in the larger definitive efficacy study.

"*S. aureus* continues to be cited by the World Health Organization and other health regulatory agencies as a high priority pathogen due to its evolving resistance to modern antibiotics and the significant socioeconomic challenges that it poses to healthcare systems," stated Mina Pastagia, MD, MS, Chief Medical Officer of Armata. "Results from diSArm will be an important step forward in our effort to confirm the potent antimicrobial activity of phage therapy. We aspire to introduce intravenous AP-SA02 as part of a new class of anti-infectives to a patient population that often faces metastatic infections with suboptimal treatment options. I would like to thank the investigators and patients who have participated in diSArm, as well as our partners at Medical Technology Enterprise Consortium (MTEC) and Naval Medical Research Command (NMRC) – Naval Advanced Medical Development (NAMD). As with all of Armata's phage clinical trials, the insights gained for local and systemic phage administration are invaluable to us and to the field as we approach pivotal trials next year."

Armata remains committed to developing a pivotal *S. aureus* bacteremia trial in 2025 to evaluate the intravenous phage product candidate, AP-SA02, as an adjunct to standard of care broad-spectrum antibiotics and/or potentially as an alternative to broad-spectrum antibiotics. Modern medicine requires a hard look at reliance on broad-spectrum antibiotics and their detrimental impact on the healthy human microbiome. The Company plans to discuss its pivotal trial design with the U.S. Food and Drug Administration.

The clinical development of AP-SA02 is supported in part by $21.6 million funds from the Defense Health Agency and Joint Warfighter Medical Research Program received through the MTEC and managed by the NMRC-NAMD.

The diSArm study is a Phase 1b/2a, randomized, double-blind, placebo-controlled, multiple ascending dose escalation study of the safety, tolerability, and efficacy of intravenous AP-SA02 as an adjunct to best available antibiotic therapy (BAT) compared to BAT alone for the treatment of adults with bacteremia due to *S. aureus*. The Phase 1b portion evaluated the safety and tolerability of multiple ascending intravenous doses of AP-SA02 or placebo as an adjunct to BAT compared to BAT alone in subjects with *S. aureus* bacteremia. The Phase 2a portion evaluated the efficacy, safety, and tolerability of multiple doses of intravenous AP-SA02 or placebo as an adjunct to BAT compared to BAT alone in subjects with complicated *S. aureus* bacteremia.

For more information: https://clinicaltrials.gov/study/NCT05184764?term=diSArm&rank=1

About Armata Pharmaceuticals, Inc.

Armata is a clinical-stage biotechnology company focused on the development of pathogen-specific bacteriophage therapeutics

for the treatment of antibiotic-resistant and difficult-to-treat bacterial infections using its proprietary bacteriophage-based technology. Armata is developing and advancing a broad pipeline of natural and synthetic phage candidates, including clinical candidates for *Pseudomonas aeruginosa*, *Staphylococcus aureus*, and other pathogens. Armata is committed to advancing phage therapy with drug development expertise that spans bench to clinic including in-house phage specific cGMP manufacturing.

Forward Looking Statements

This communication contains "forward-looking" statements as defined by the Private Securities Litigation Reform Act of 1995. These statements relate to future events, results or to Armata's future financial performance and involve known and unknown risks, uncertainties and other factors which may cause Armata's actual results, performance or events to be materially different from any future results, performance or events expressed or implied by the forward-looking statements. In some cases, you can identify these statements by terms such as "anticipate," "believe," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "should," "will," "would" or the negative of those terms, and similar expressions. These forward-looking statements reflect management's beliefs and views with respect to future events and are based on estimates and assumptions as of the date of this communication and are subject to risks and uncertainties including risks related to Armata's development of bacteriophage-based therapies; ability to staff and maintain its production facilities under fully compliant current Good Manufacturing Practices; ability to meet anticipated milestones in the development and testing of the relevant product; ability to be a leader in the development of phage-based therapeutics; ability to achieve its vision, including improvements through engineering and success of clinical trials; ability to successfully complete preclinical and clinical development of, and obtain regulatory approval of its product candidates and commercialize any approved products on its expected timeframes or at all; and Armata's estimates regarding anticipated operating losses, capital requirements and needs for additional funds. Additional risks and uncertainties relating to Armata and its business can be found under the caption "Risk Factors" and elsewhere in Armata's filings and reports with the SEC, including in Armata's Annual Report on Form 10-K, filed with the SEC on March 21, 2024, and in its subsequent filings with the SEC.

Armata expressly disclaims any obligation or undertaking to release publicly any updates or revisions to any forward-looking statements contained herein to reflect any change in Armata's expectations with regard thereto or any change in events, conditions or circumstances on which any such statements are based.

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