

Armata Pharmaceuticals Announces End-of-Phase 2 Meeting with FDA and Plans to Advance AP-SA02 to a Phase 3 Superiority Study in Complicated *Staphylococcus aureus* Bacteremia

FDA agreed that data from the Phase 2a diSArm study support advancement of AP-SA02 to a Phase 3 study

First bacteriophage company to advance a clinical candidate to Phase 3

LOS ANGELES, Jan. 13, 2026 /PRNewswire/ -- Armata Pharmaceuticals, Inc. (NYSE American: ARMP) ("Armata" or the "Company"), a late clinical-stage biotechnology company focused on the development of high-purity, pathogen-specific bacteriophage therapeutics for the treatment of antibiotic-resistant and difficult-to-treat bacterial infections, today announced the conclusion of an End-of-Phase 2 ("EOP2") written response from the U.S. Food and Drug Administration ("FDA") and plans to advance the Company's intravenously-administered *Staphylococcus aureus* bacteriophage product candidate, AP-SA02, into a Phase 3 clinical study in complicated *S. aureus* bacteremia. The Phase 3 study is anticipated to initiate in the second half of 2026.

FDA's Center for Biologics Evaluation and Research division, upon reviewing Armata's detailed EOP2 background package, confirmed that the safety and efficacy data from Armata's Phase 2a diSArm study support advancement to Phase 3. The FDA provided critical guidance on key elements of the Phase 3 study design, which will assess the superiority of AP-SA02 over the current standard of care for the treatment of complicated *S. aureus* bacteremia. Armata is addressing FDA comments, including on Chemistry, Manufacturing, and Controls ("CMC") and aligning them with the Company's existing Phase 3 manufacturing and quality strategy. The FDA also included recommendations for the future Biologics License Application and is amenable to Armata submitting a request for Qualified Infectious Disease Product Designation ("QIDP") for AP-SA02. The Company is already addressing many of the clinical and CMC comments from FDA and has submitted the request for QIDP.

"The completion of our Phase 2a diSArm was the first evidence of the efficacy of phage therapy in a randomized controlled study and a momentous achievement for Armata," stated Dr. Deborah Bix, Chief Executive Officer of Armata. "Following the End-of-Phase 2 meeting written response from FDA, in which the FDA provided recommendations on key study elements, we can finalize the design of the pivotal superiority study of AP-SA02. Armata intends to initiate the study later this year. If successful, this would be the first superiority-based pivotal trial for an antibacterial drug candidate in several decades and usher in a new era in the treatment of deadly bacterial infections such as complicated bacteremia due to *S. aureus*."

"I would like to acknowledge the participants and investigators from the diSArm study who were critical in getting us to this point. The Company anticipates robust enrollment in the Phase 3 study in light of the Phase 2 data, and many sites that participated in the Phase 2 study are enthusiastic to continue to be involved. We remain grateful for our partnership with the U.S. Department of Defense, and our significant shareholder, Innoviva, who continue to support this important program," Dr. Bix concluded.

The results of the Phase 2a diSArm study were announced in May 2025 and further highlighted in a late-breaking oral [presentation at IDWeek 2025™](#) in October 2025. The primary study endpoint for the Phase 3 superiority study is expected to be clinical response at end of best available antibiotic therapy ("BAT") and 28 days later at End of Study. Safety and healthcare resource impact analyses will be included.

About AP-SA02 and diSArm Study

Armata is developing AP-SA02, a fixed multi-phage phage cocktail, for the treatment of complicated bacteremia caused by *Staphylococcus aureus*, including methicillin-sensitive *S. aureus* (MSSA) and methicillin-resistant *S. aureus* (MRSA) strains.

The diSArm study ([NCT05184764](#)) was a Phase 1b/2a, multicenter, randomized, double-blind, placebo-controlled, multiple ascending dose escalation study of the safety, tolerability, and efficacy of intravenous AP-SA02 in addition to BAT compared to BAT alone (placebo) for the treatment of adults with complicated *S. aureus* bacteremia. The results from the diSArm study are an important step forward in Armata's effort to confirm the potent antimicrobial activity of phage therapy and the completion of the study represents a significant milestone in the development of AP-SA02, moving Armata one step closer to introducing an effective new treatment option to patients suffering from complicated *S. aureus* bacteremia.

The Phase 1b/2a clinical development of AP-SA02 was partially supported by a \$26.2 million Department of Defense (DoD) award, received through the Medical Technology Enterprise Consortium (MTEC) and managed by the Naval Medical Research Command (NMRC) – Naval Advanced Medical Development (NAMD) with funding from the Defense Health Agency and Joint Warfighter Medical Research Program.

About Armata Pharmaceuticals, Inc.

Armata is a late clinical-stage biotechnology company focused on the development of high-purity 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 important pathogens. Armata is committed to advancing phage therapy with drug development expertise that spans bench to clinic including in-house phage-specific current Good Manufacturing Practices ("cGMP") manufacturing to support full commercialization.

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; Armata's planned clinical trials; ability to staff and maintain its production facilities under fully compliant cGMP; 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 U.S. Securities and Exchange Commission (the "SEC"), including in Armata's Annual Report on Form 10-K, filed with the SEC on March 21, 2025, 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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Correction: *An earlier version of this release incorrectly had the headline as 'Complicated BacteremiaStaphylococcus aureus' instead of 'Complicated Staphylococcus aureus Bacteremia.'*

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