

Armata Pharmaceuticals Receives Agreement from FDA on Initial Pediatric Study Plan for AP-SA02 for the Treatment of Complicated *Staphylococcus aureus* Bacteremia

Fulfills important regulatory milestone for AP-SA02 on the path toward a future BLA and supports expansion into pediatric patients

LOS ANGELES, July 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 that it has received agreement from the U.S. Food and Drug Administration (the "FDA") on an Agreed Initial Pediatric Study Plan ("Agreed iPSP"), which establishes the agreed regulatory framework for the future evaluation of AP-SA02 for the adjunct treatment of complicated *Staphylococcus aureus* bacteremia ("SAB") in pediatric patients. Agreement with the FDA on an iPSP is a regulatory requirement that must be met prior to submitting a Biologics License Application ("BLA").

"Reaching agreement with the FDA on our Agreed iPSP for AP-SA02 is an important regulatory milestone that reflects our commitment to addressing the needs of both adult and pediatric patients with complicated SAB," said Dr. Deborah Birx, Chief Executive Officer of Armata. "Pediatric patients, especially very young premature babies and newborns, represent a particularly vulnerable population with limited treatment options for serious *S. aureus* infections, and we are pleased to have an aligned, FDA-endorsed pediatric development framework in place. This agreement positions us to work towards efficiently expanding development beyond adults while continuing to advance AP-SA02 toward potential registration."

The Agreed iPSP outlines a proposed pediatric development program targeting patients up to 17 years of age with complicated SAB, the same indication that Armata is pursuing in adults. Consistent with FDA requirements under the Pediatric Research Equity Act (PREA) and with established FDA and European Medicines Agency regulatory frameworks, the FDA agreed that because the disease pathophysiology and treatment response in SAB are consistent across all age groups, pediatric studies should be deferred until safety and efficacy data are generated in adults in the planned Phase 3 program. Following completion of the adult Phase 3 study which is expected to initiate in the second half of 2026, the proposed program will comprise a single, multicenter, open-label, pediatric study to assess safety, tolerability, and clinical response outcomes. This strategy establishes a pathway for potential future expansion of AP-SA02 into the pediatric population while prioritizing patient safety and efficient clinical development.

About AP-SA02

Armata is developing AP-SA02, a fixed multi-phage cocktail, for the adjunct treatment of complicated *Staphylococcus aureus* bacteremia caused by methicillin-sensitive *S. aureus* (MSSA) or methicillin-resistant *S. aureus* (MRSA). AP-SA02 has received [Qualified Infectious Disease Product \(QIDP\)](#), and [Fast Track](#) designations from the FDA. 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 best available antibiotic therapy ("BAT") compared to BAT alone (placebo) for the treatment of adults with complicated *S. aureus* bacteremia. [Positive results](#) from the Phase 2a diSArm study were highlighted in a [late-breaking oral presentation at IDWeek 2025™](#) in October 2025. The Company plans to advance AP-SA02 into a Phase 3 superiority study in complicated *S. aureus* bacteremia, anticipated to initiate in the second half of 2026.

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*, *S. 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 25, 2026, 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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