

Armata Pharmaceuticals Secures FDA Fast Track Designation for AP-SA02

Enables more frequent FDA engagement, rolling Biologic License Application review, and the potential for Accelerated Approval and Priority Review upon successful clinical development

Advances AP-SA02 on a faster path to potential approval and patient access

LOS ANGELES, May 7, 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 the U.S. Food and Drug Administration (the "FDA") has granted Fast Track Designation to AP-SA02, the Company's intravenously administered *Staphylococcus aureus* ("*S. aureus*") multi-phage product candidate, for adjunct treatment of complicated bacteremia caused by methicillin-sensitive *S. aureus* ("MSSA") or methicillin resistant *S. aureus* ("MRSA").

"We are pleased to receive Fast Track designation from the FDA for AP-SA02, which marks another important milestone for this program and underscores both the seriousness of complicated *S. aureus* bacteremia ("SAB") and the urgent need for effective new treatment options," said Dr. Deborah Bix, Chief Executive Officer of Armata Pharmaceuticals. "This designation recognizes the potential of AP-SA02 to improve upon current standard of care treatment options for complicated SAB, a common, extremely severe, and often deadly infection, and highlights the strength of Armata's phage platform to deliver differentiated therapies for bacterial infections. As we advance toward the initiation of our Phase 3 superiority study, anticipated to begin in the second half of 2026, we remain focused on executing efficiently and look forward to interacting more frequently with the FDA throughout the clinical development and review process, with the goal of bringing this novel antibacterial therapy to patients as quickly as possible."

Fast Track designation is intended to facilitate the development and expedite the review of investigational therapies that treat serious conditions and fill an unmet medical need. The designation provides for more frequent interactions with the FDA regarding all aspects of a designated drug's clinical development program, supporting a more efficient path to registration. Fast Track designation also allows for rolling review of a Biologics License Application ("BLA"), meaning completed sections may be submitted and reviewed on an ongoing basis rather than waiting for the full application. Additionally, Fast Track-designated programs may also be eligible for Accelerated Approval and Priority Review if supported by clinical data at the time of BLA submission, further supporting a faster path to potential approval and patient access. For more information on the Fast Track designation, visit the [FDA's official website](#).

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). 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 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. 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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