# Armata Pharmaceuticals Announces Clearance of Investigational New Drug (IND) Application to Initiate Phase 1b/2a Clinical Trial of Lead Candidate AP-PA02 in Pseudomonas aeruginosa Infections

Upcoming study, to be known as "SWARM-P.a.," is believed to be first FDA cleared, controlled clinical trial to evaluate a multiple phage-based mixture as a therapeutic candidate in Cystic Fibrosis patients

MARINA DEL REY, Calif., Oct. 15, 2020 / PRNewswire/ -- Armata Pharmaceuticals, Inc. (NYSE American: ARMP) ("Armata" or the "Company"), a biotechnology company focused on precisely targeted bacteriophage therapeutics for antibiotic-resistant and difficult-to-treat bacterial infections, today announced that the U.S. Food and Drug Administration (FDA) has cleared Armata's IND to initiate a clinical trial of its lead therapeutic candidate, AP-PA02, in *Pseudomonas aeruginosa* infections.

"We are very pleased that the FDA has cleared our IND, and we plan to initiate clinical development of AP-PA02 by the end of this year, consistent with our original guidance notwithstanding disruptions to drug development timelines across the industry caused by the COVID-19 pandemic," stated Todd R. Patrick, Chief Executive Officer of Armata Pharmaceuticals. "Results from this study, which we are calling SWARM-*P.a.* to reflect the manner in which phage attack dangerous pathogens, will be our Company's first clinical trial to evaluate a phage-based therapy as a potential treatment for *Pseudomonas aeruginosa* airway infections. This clinical trial will contribute to the evaluation of the potential of phage to combat multi-drug resistant infections, and potentially usher in a new era in the fight to develop alternatives to antibiotics."

"Pseudomonas aeruginosa infections are particularly dangerous for cystic fibrosis patients, and I would once again like to express my gratitude to the CF Foundation for the important financial and clinical support that they are providing to help advance this candidate through clinical trials as efficiently as possible. While the study will initially evaluate AP-PA02 in combination with standard antibiotics, our ultimate goal with this product candidate is to replace antibiotics as a front-line therapy," Mr. Patrick concluded.

The SWARM-*P.a.* study will be a Phase 1b/2a, multi-center, double-blind, randomized, placebo-controlled, single ascending dose (SAD) and multiple ascending dose (MAD) clinical trial to evaluate the safety and tolerability of inhaled AP-PA02 in subjects with cystic fibrosis and chronic pulmonary *Pseudomonas aeruginosa* infection. Barring worsening COVID-19 conditions, Armata expects to initiate the SAD cohort by the end of this year.

# **About Armata Pharmaceuticals, Inc.**

Armata is a clinical-stage biotechnology company focused on the development of precisely targeted 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. In addition, in collaboration with Merck, known as MSD outside of the United States and Canada, Armata is developing proprietary synthetic phage candidates to target an undisclosed infectious disease agent. Armata is committed to advancing phage with drug development expertise that spans bench to clinic including in-house phage specific GMP manufacturing.

# **Forward Looking Statements**

This communication contains "forward-looking" statements, including, without limitation, statements related to Armata's ability to meet expected milestones, expand its pipeline, and pursue additional potential partnerships, the expected use of proceeds from the recent \$15 million grant, Armata's ability to be a leader in the development of phage-based therapeutics, statements related to the timing and results of clinical trials, including the anticipated initiation of clinical trials of AP-PA02 and AP-SA02, expected impact of the COVID-19 pandemic on the Company's operations, Armata's ability to develop new products based on bacteriophages and synthetic phages, the timing and ability of Armata to obtain non-dilutive funding on acceptable terms, if at all, Armata's expectations for performance of Armata's therapeutic candidates based on Armata's recent nonclinical work, and Armata's ability to continue to screen pathogens against Armata's proprietary phage library to identify additional high-quality bacteriophage product candidates and expand the pipeline. Any statements contained in this communication that are not statements of historical fact may be deemed to be forward-looking statements. These forward-looking statements are based upon Armata's current expectations. Forward-looking statements involve risks and uncertainties. Armata's actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of these risks and uncertainties, which include, without limitation, risks related to the ability of Armata's lead clinical candidates,

AP-PA02 and AP-SA02, to be more effective than previous candidates; Armata's ability to expedite development of AP-PA02; Armata's ability to advance its preclinical and clinical programs and the uncertain and time-consuming regulatory approval process; Armata's ability to develop products based on bacteriophages and synthetic phages to kill bacterial pathogens; Armata's expected market opportunity for its products; Armata's ability to sufficiently fund its operations as expected, including obtaining additional funding as needed; and any delays or adverse events within, or outside of, Armata's control, caused by the recent outbreak of COVID-19. 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 19, 2020, 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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