

Armata Pharmaceuticals Announces Positive Topline Data from Phase 1b/2a SWARM-P.a. Clinical Trial of Inhaled AP-PA02 in Patients with Cystic Fibrosis

AP-PA02 is well-tolerated and data supports progression to Phase2b

Also announces first subject dosed in Phase 2 'Tailwind' clinical trial of inhaled AP-PA02 in patients with Non-Cystic Fibrosis Bronchiectasis (NCFB)

NCFB represents Armata's third active clinical program

MARINA DEL REY, Calif., March 6, 2023 [/PRNewswire/](#) -- Armata Pharmaceuticals, Inc. (NYSE American: ARMP) ("Armata" or the "Company"), a biotechnology company focused on pathogen-specific bacteriophage therapeutics for antibiotic-resistant and difficult-to-treat bacterial infections, today announced positive topline results from the completed Phase 1b/2a SWARM-*P.a.* trial evaluating AP-PA02, a novel, inhaled multi-phage therapeutic for the treatment of chronic pulmonary *Pseudomonas aeruginosa* infections in cystic fibrosis patients.

"We are pleased to present topline data for our lead multi-phage candidate, AP-PA02, which was evaluated in cystic fibrosis patients in the SWARM-*P.a.* clinical trial, and to announce the dosing of the first subject in our *Tailwind* study of AP-PA02 in NCFB," stated Mina Pastagia, MD, MS, Chief Medical Officer at Armata. "The data from our SWARM-*P.a.* study gives us confidence that the pharmacokinetics of inhaled phage are predictable and suggest that optimized exposures will correlate with bacterial load reduction. CF and NCFB are chronic pulmonary disorders in which the bronchi become permanently dilated due to a cycle of mucus production, inflammation, and lung tissue damage. The airways often then become colonized by *Pseudomonas aeruginosa*, with the same bacterial lineage persisting in the lungs of patients for decades despite the use of life-long inhaled antibiotics."

The SWARM-*P.a.* trial was a multi-center, randomized, double-blind, placebo-controlled, single- and multiple-ascending dose study that evaluated the safety, tolerability, pharmacokinetics (PK) and pharmacodynamics (PD) of AP-PA02.

Data indicate that AP-PA02 was well-tolerated with a treatment emergent adverse event (TEAE) profile similar to placebo. Only mild, self-limited adverse events possibly related to study drug were reported in a few subjects.

PK findings confirm that AP-PA02 can be effectively delivered to the lungs through nebulization with minimal systemic exposure. Single ascending doses (SAD) and multiple ascending doses (MAD) resulted in a proportional increase in exposure as measured in induced sputum. Additionally, achieved exposures were relatively consistent from subject to subject.

Bacterial levels of *P. aeruginosa* in the sputum were measured at several timepoints and compared to baseline levels prior to study drug administration. Trends suggest improvement in bacterial load reduction for subjects treated with AP-PA02 at end of treatment as compared to placebo after ten days of dosing. Importantly, for subjects with the highest average exposure of susceptible phage, there was durability of approximately two-log reduction from end of treatment to end of study (day 28 post dose). PK/PD analysis indicates significant microbiological impacts in the subjects with highest exposures.

Armata also announced today that it has dosed the first subject in its *Tailwind* study of nebulized AP-PA02 in patients with non-cystic fibrosis bronchiectasis (NCFB). The *Tailwind* study ([NCT05616221](#)) is a double blind, randomized, placebo-controlled trial that will evaluate the safety, tolerability, and efficacy of inhaled AP-PA02 as monotherapy, as well as in combination with inhaled antibiotics. Pharmacokinetic data from SWARM-*P.a.* were used to design an optimized AP-PA02 dosing regimen for the *Tailwind* study. Insights from *Tailwind* will be important for the concurrent design of the Phase2b cystic fibrosis study, which will be powered to evaluate the efficacy and durability of phage response over time.

"Data from *Tailwind*, together with our recently completed SWARM-*P.a.* trial, are intended to provide further evidence of the clinical value of phage therapy as a novel approach for the treatment of chronic, biofilm-related respiratory infections, and will hopefully move Armata one step closer to establishing phage as a new and powerful class of anti-infectives," stated Dr. Pastagia.

"The initiation of patient dosing in the *Tailwind* study represents our third active clinical program, highlighting our commitment to bring much needed innovation to clinical indications where antibiotic therapy is failing," stated Dr. Brian Varnum, Chief Executive Officer of Armata. "In addition to our recently completed SWARM-*P.a.* study, we have line-of-sight to two additional data readouts that can potentially provide new hope to patients suffering from serious and difficult to treat bacterial infections."

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 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 bacteriophage development programs, Armata's ability to set up or operate R&D and manufacturing facilities, Armata's ability to meet expected milestones, Armata's ability to be a leader in the development of phage-based therapeutics, and statements related to the timing and results of clinical trials, including the anticipated results of clinical trials of AP-PA02 and AP-SA02, and Armata's ability to develop new products based on bacteriophages and synthetic phages. 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; that the top line results are indicative of the final data, 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; the Company'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 ongoing COVID-19 pandemic. 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 17, 2022, 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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