



# azitra

## Azitra, Inc. Announces Positive Preclinical Data from ATR-04 Presented at the Society of Investigative Dermatology Annual Meeting

May 17, 2024 12:00 PM EDT

- ATR-04 is in development for epidermal growth factor receptor inhibitor (EGFRI)-induced dermal toxicity, which affects approximately 150,000 patients in the US
- Reduces methicillin-resistant *S. aureus* by 99% on *ex vivo* pig skin
- Reduces IL-36g, a pro-inflammatory cytokine that drives inflammation in EGFRI-induced toxicity, in human skin model by 75% compared to erlotinib-treated skin
- Increases human beta defensin 18-fold vs. vehicle on human skin model

BRANFORD, Conn.—(BUSINESS WIRE)—May 17, 2024—Azitra, Inc. (NYSE American: AZTR), a clinical-stage biopharmaceutical company focused on developing innovative therapies for precision dermatology, today announced preclinical data from the Company's platform and pipeline. The data are being presented on Friday, May 17, 2024, in two oral sessions entitled "Staphylococcus epidermidis for the topical treatment of epidermal growth factor receptor (EGFR) inhibitor-induced dermal toxicity" and "Cutaneous delivery of LEKTI via an engineered strain of Staphylococcus epidermidis for the treatment of Netherton syndrome" at the Society of Investigative Dermatology (SID) 2024 Annual Meeting in Dallas, TX.

"We are pleased to announce the first publication of preclinical data around ATR-04 in EGFR inhibitor (EGFRI)-associated dermal toxicity," said Travis Whitfill, Azitra's co-founder and COO. "These data show robust preclinical activity of ATR-04 in models of EGFRI-induced dermal toxicities that support an upcoming Investigational New Drug (IND) application to the FDA for a Phase 1b in patients undergoing EGFR inhibitors with dermal toxicity. We anticipate the expansion of our clinical-stage pipeline this year with ATR-04."

ATR-04 is a live biotherapeutic product candidate consisting of an *S. epidermidis* strain that was isolated from a healthy volunteer and engineered to be safer by deleting an antibiotic resistance gene and engineering auxotrophy to control the growth of ATR-04. ATR-04 is in development for EGFRI-associated skin toxicity, which is caused by the suppression of skin immunity by EGFRI and subsequent inflammation and often elevated levels of IL-36g and *S. aureus*. There are approximately 150,000 patients suffering from EGFRI-induced skin toxicity in the United States.

The data in the oral presentations today showcase the preclinical development of ATR-04. ATR-04 led to a decrease in *S. aureus* across multiple models. In *in vitro* skin models, ATR-04 treatment led to a 96% reduction in methicillin-resistant *S. aureus* (MRSA) compared to untreated skin ( $p < 0.0001$ ). In *ex vivo* pig skin treated with ATR-04, there was a ~99% reduction in MRSA compared to untreated skin ( $p = 0.012$ ). Additionally, in human skin models treated with erlotinib, an EGFRI, ATR-04 reduced IL-36g by 75% ( $p = 0.009$ ) to levels comparable to untreated skin models. Finally, ATR-04 increased human beta defensin, a key protein involved in host defenses, by 18-fold compared to vehicle. Together, the data show that ATR-04 can address multiple drivers of EGFRI-induced skin toxicity.

The presentations are now available on Azitra's website at <https://ir.azitrainc.com/news-events/presentations>.

### About Azitra, Inc.

Azitra, Inc. is an early-stage clinical biopharmaceutical company focused on developing innovative therapies for precision dermatology using engineered proteins and topical live biotherapeutic products. The Company has built a proprietary platform that includes a microbial library comprised of approximately 1,500 unique bacterial strains that can be screened for unique therapeutic characteristics. The platform is augmented by artificial intelligence and machine learning technology that analyzes, predicts, and helps screen the Company's library of strains for drug like molecules. The Company's initial focus is on the development of genetically engineered strains of *Staphylococcus epidermidis*, or *S. epidermidis*, which the Company considers to be an optimal therapeutic candidate species for engineering of dermatologic therapies. For more information, please visit <https://azitrainc.com/>.

### Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended. These statements may be identified by words such as "aims," "anticipates," "believes," "could," "estimates," "expects," "forecasts," "goal," "intends," "may," "plans," "possible," "potential," "seeks," "will," and variations of these words or similar expressions that are intended to identify forward-looking statements. Any such statements in this press release that are not statements of historical fact may be deemed to be forward-looking statements. These forward-looking statements include, without limitation, statements regarding the advancement of ATR-04 into a Phase 1b clinical trial; expectation that the initial pre-clinical data for ATR-04 will be consistent with the further pre-clinical data, and the benefits of the Company's proprietary platform and microbial library.

Any forward-looking statements in this press release are based on current expectations, estimates and projections only as of the date of this release and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those set forth in or implied by such forward-looking statements. These risks and uncertainties include, but are not limited to (i) the risk that the further data from the ongoing pre-clinical trial for ATR-04 will not be favorably consistent with the initial pre-clinical data to date, (ii) the risk that the Company's IND application for ATR-04 may not receive a safe to proceed letter from the FDA, (iii) success in early phases of pre-clinical trials do not ensure later clinical trials will be successful; we may fail to timely raise additional required funding; and those additional risks concerning Azitra's programs and operations are described in its annual report on Form 10-K filed with the SEC on March 15, 2024. Azitra explicitly disclaims any obligation to update any forward-looking statements except to the extent required by law.

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