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Azitra, Inc. Advances ATR-04 Phase 1/2 Clinical Trial to Cohort 2 Following Safety Review Committee Clearance

October 1, 2026 12:00 PM EDT

BRANFORD, Conn., Oct. 1, 2026 /PRNewswire/ -- Azitra, Inc. ("Azitra" or the "Company") (NYSE American: AZTR), a clinical-stage biopharmaceutical company focused on developing innovative therapies for precision dermatology, today announced the completion of Cohort 1 in its Phase 1/2 clinical trial evaluating ATR04-484 as a potential treatment for EGFR inhibitor (EGFRI)-associated skin rash. Following its review of available safety data from patients enrolled in Cohort 1, the study's safety review committee recommended that the trial may proceed to Cohort 2, enabling Azitra to begin enrollment and dosing in the second cohort.



The multicenter, randomized, double-blind, vehicle-controlled Phase 1/2 clinical study ([NCT06830863](https://clinicaltrials.gov/ct2/show/study/NCT06830863)) is designed to evaluate the safety and tolerability of topical ATR-04 for the treatment of EGFRI-associated dermal toxicity affecting adult patients. The safety, bioavailability, pharmacodynamics, and preliminary efficacy of ATR04-484 are being compared to its vehicle (3:1 randomization) in two patient cohorts. Seven patients in Cohort 1 received a single 4g application of ATR04-484 to the face, chest and back, followed by a 7-day observation period then once-daily application for 28 days. Cohort 2 is expected to enroll approximately 24 patients who will receive a 4g application once daily for 28 days. The study is currently being conducted at six clinical sites, including MD Anderson Cancer Center and Yale University. The safety review was based on six patients.

"Proceeding to Cohort 2 following the safety review committee's review of Cohort 1 data represents an important milestone for our ATR-04 program," said Francisco Salva, Chief Executive Officer of Azitra. "We believe ATR-04 has the potential to become the first live biotherapeutic specifically developed to address cancer treatment-associated rash, a debilitating side effect that impacts thousands of cancer patients and can disrupt life-saving treatment. With positive safety data from the first cohort, we are focused on advancing into the next phase of the trial."

EGFR inhibitors have become an important component of treatment for several cancers, including non-small cell lung cancer and colorectal cancer. However, these targeted therapies frequently cause a painful papulopustular skin rash that affects approximately 50-80% of patients. The severity of the rash can significantly impair quality of life and often leads to dose reductions, treatment interruptions or discontinuation of otherwise effective cancer therapies, underscoring the need for new treatment options.

About Azitra's ATR-04 Program

ATR04-484 is a live biotherapeutic product candidate including an isolated, naturally derived *Staphylococcus epidermidis* strain in development for EGFRI-associated skin rash. The candidate was selected based on its preclinical profile of reducing IL-36γ and *Staphylococcus aureus* levels, both of which are elevated in patients with EGFRI-associated skin rash. The strain was then engineered with the aim of improving its safety profile by deleting an antibiotic resistance gene and engineering auxotrophy to control the growth of ATR04. Preclinical data have shown that ATR04-484 can reduce levels of IL-36γ, a key pro-inflammatory cytokine elevated in these rashes. ATR04-484 has also been shown to inhibit the growth of *S. aureus* in preclinical studies, which often colonizes the skin of affected patients. The U.S. Food and Drug Administration (the "FDA") has granted Fast Track designation to ATR04-484 for the treatment of EGFRI-associated rash, recognizing the high unmet medical need for the approximately 150,000 patients affected annually in the United States.

About Azitra, Inc.

Azitra, Inc. is a clinical-stage biopharmaceutical company focused on developing innovative therapies for precision dermatology and novel products across therapeutics, cosmeceuticals and biotechnology applications. The Company's portfolio is highlighted by ATR-COSF, a recombinant protein technology designed for cosmetic and skincare applications, and ATR-04, an investigational live biotherapeutic for EGFRI inhibitor associated rash. Azitra has received Fast Track designation from the FDA for EGFRI-associated rash, which impacts approximately 150,000 people in the U.S. Azitra is also advancing additional recombinant protein initiatives designed to support biotechnology research and manufacturing applications. Azitra's technology platforms combine engineered proteins, topical live biotherapeutics, artificial intelligence, and a proprietary microbial library to develop differentiated products for consumer, research and healthcare markets. 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," "would," "target," "continue," "ongoing" 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 (i) the expected enrollment, dosing and conduct of Cohort 2 of the Phase 1/2 clinical trial of ATR-04, (ii) the safety and preliminary efficacy data from the trial, (iii) the potential of ATR-04 to treat EGFRI-associated skin rash, including its potential to be the first live biotherapeutic developed for this indication, (iv) the size of the potential patient population and the potential benefits of Fast Track designation, and (v) statements about our clinical and preclinical programs, and corporate and clinical/preclinical strategies, including our cosmeceutical strategy.

You should not place undue reliance on any forward-looking statements. 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: the timing of clinical trials and their results; we may experience enrollment delays; we may experience delays in the provision of initial or additional safety data, as applicable, and topline results for ATR-04 and, if we do, such data and results may not be favorably received; the results from Cohort 1 may not be predictive of results in Cohort 2 or later-stage trials; the safety and efficacy of our product candidates; possible delays in regulatory approval or changes in regulatory framework that are out of our control; our estimation of addressable markets of our product candidates may be inaccurate; we may fail to timely raise additional required funding; more efficient competitors or more effective competing treatment may emerge; we may be involved in disputes surrounding the use of our intellectual property crucial to our success; we may not be able to attract and retain key employees and qualified personnel; earlier study results may not be predictive of later stage study outcomes; and we are dependent on third-parties for some or all aspects of our product manufacturing, research and preclinical and clinical testing. Additional risks concerning Azitra's programs and operations are described or incorporated by reference in our annual report on Form 10-K filed with the United States Securities and Exchange Commission (the "SEC") on February 27, 2026 and our quarterly report on Form 10-Q filed on August 12, 2026 with the SEC. Azitra explicitly disclaims any obligation to update any forward-looking statements to reflect events or circumstances that occur after the date hereof, except to the extent required by law.

Contact

Norman Staskey
Chief Financial Officer
staskey@azitrainc.com

Investor Relations

Tiberend.Strategic.Advisors.Inc
David Irish
231-632-0002
d Irish@tiberend.com

Media Relations

Tiberend.Strategic.Advisors.Inc
Casey McDonald
646-577-8520
cmcdonald@tiberend.com

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SOURCE: Azitra, Inc.