



azitra

Azitra, Inc. Announces First Patient Dosed in Phase 1/2 Trial for ATR-04 Program Targeting Oncology Patients with EGFR-Associated Rash

August 27, 2025 12:10 PM EDT

BRANFORD, Conn., Aug. 27, 2025 /PRNewswire/ -- Azitra, Inc. ("Azitra") (NYSE American: AZTR), a clinical stage biopharmaceutical company focused on developing innovative therapies for precision dermatology, today announced the dosing of the first patient in its Phase 1/2 clinical trial of ATR04-484, a topically applied live biotherapeutic product candidate designed to treat EGFR inhibitor ("EGFR")-associated rash. Azitra has received Fast Track designation from the FDA for EGFR associated rash, which impacts approximately 150,000 people in the U.S. annually.



"Dosing the first patient is an important milestone in the advancement of ATR04-484 as a potential treatment for EGFR associated rash and in the development of our broader ATR-04 technology program," said Francisco Salva, CEO of Azitra. "Given the importance of EGFR treatments across multiple cancers, there is a critical medical need to reduce the impact of the unique dermatologic toxicities that often accompany EGFR treatments, often leading to interruption or discontinuation of the treatment. This trial is a first step in ATR04-484 potentially addressing this patient need and market opportunity."

Targeted cancer therapies, like EGFRs, have produced significant treatment advances for patients diagnosed with a variety of tumor types including non-small cell lung cancer (NSCLC) and colorectal cancer, but they are also associated with unique dermatologic toxicities. These side effects can severely hamper treatment efforts, causing significant physical and psychological discomfort for patients. The papulopustular rash is often the earliest and most common dermatologic adverse event of EGFR treatment and can occur in 50-80% of patients, often impacting quality of life severely enough to interrupt or stop cancer treatment.

The multicenter, randomized, double-blind, vehicle-controlled Phase 1/2 clinical study (NCT06930963) is designed to evaluate the safety and tolerability of topical ATR04-484 for the treatment of EGFR-associated dermal toxicity affecting the face of adult patients. ATR04-484 or its vehicle (3:1 randomization) will be applied to the face as well as affected areas on the neck, chest, back, and areas around nailbeds. The key objectives of the study will be to assess the safety and tolerability of topical ATR04-484 and to evaluate efficacy signals including severity of disease, pruritus, and pain. The bioavailability of ATR04-484 and pharmacodynamic parameters will also be studied. This clinical study will establish the basis for continued clinical development of ATR04-484.

ATR04-484 is a live biotherapeutic product candidate including an isolated, naturally derived *Staphylococcus epidermidis* strain in development for EGFR-associated skin rash. The candidate was selected based on its preclinical profile of reducing IL-36 γ and *S. aureus* levels, both of which are elevated in patients with EGFR-associated skin rash. The strain was then engineered to be safe by deleting an antibiotic resistance gene and engineering auxotrophy to control the growth of ATR04-484.

About Azitra, Inc.

Azitra, Inc. is a clinical stage biopharmaceutical company focused on developing innovative therapies for precision dermatology. Azitra's lead program, ATR-12, uses an engineered strain of *S. epidermidis* designed to treat Netherton syndrome, a rare, chronic skin disease with no approved treatment options. Netherton syndrome may be fatal in infancy with those living beyond a year having profound lifelong challenges. The ATR-12 program includes a Phase 1b clinical trial in adults with Netherton syndrome. ATR-04, Azitra's additional clinical program, utilizes another engineered strain of *S. epidermidis* for the treatment of EGFR inhibitor ("EGFR") associated skin toxicity; a Phase 1/2 clinical trial has been initiated for this program. Azitra has received Fast Track designation from the FDA for this program to treat EGFR associated rash, which impacts approximately 150,000 people in the United States. The ATR-12 and ATR-04 programs were developed from Azitra's proprietary platform of engineered proteins and topical live biotherapeutic products that includes a microbial library comprised of approximately 1,500 bacterial strains. The platform is augmented by artificial intelligence and machine learning technology that analyzes, predicts, and helps screen the library of strains for drug like molecules. 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 expected timing of our provision of safety data and topline results for the Phase 1b trial for our ATR-12 program, the expected timing of any additional dosing in the Phase 1/2 clinical trial for our ATR-04 program, the expected timing of any other dosing or release of data, our clinical and preclinical programs, and corporate and clinical/preclinical strategies.

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 that we may experience delays in the provision of topline results for studies of ATR-12 or ATR-04 programs, or that such data may not be favorably received; we may experience delays in dosing patients in our clinical trials; our product candidates may not be effective; there may be 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 SEC on February 24, 2025, and our subsequent quarterly reports on Form 10-Q. Azitra explicitly disclaims any obligation to update any forward-looking statements except to the extent required by law.

Contact

Norman Staskey
Chief Financial Officer
staskey@azitrainc.com

Investor Relations
[Tiberend Strategic Advisors, Inc.](https://www.tiberend.com)
Jon Nugent
205-566-3026
jnugent@tiberend.com

Media Relations
[Tiberend Strategic Advisors, Inc.](https://www.tiberend.com)
Casey McDonald
646-577-8520
cmcdonald@tiberend.com

View original content to download multimedia: <https://www.prnewswire.com/news-releases/azitra-inc-announces-first-patient-dosed-in-phase-1-2-trial-for-atr-04-program-targeting-oncology-patients-with-egfr-associated-rash-302539661.html>

SOURCE Azitra, Inc.