Azitra, Inc. Announces Addition of MD Anderson Cancer Center as Clinical Site for Phase 1/2 Trial of ATR-04 Targeting EGFRi-Associated Skin Rash

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MD Anderson Cancer Center expands ATR-04 clinical trial site footprint, offering potential to accelerate enrollment and patient treatment milestones

BRANFORD, Conn., Feb. 24, 2026 /PRNewswire/ -- Azitra, Inc. (NYSE American: AZTR), a clinical stage biopharmaceutical company focused on developing innovative therapies for precision dermatology, today announced the addition of The University of Texas MD Anderson Cancer Center as a clinical site for its ongoing Phase 1/2 clinical trial evaluating ATR-04 (ATR04-484). ATR-04 is a first-in-class, topically applied live biotherapeutic product candidate designed to treat EGFR inhibitor ("EGFRi")-associated rash.

"Expanding our clinical footprint to include MD Anderson Cancer Center, a world-renowned institution, is a significant milestone for the ATR-04 program," said Francisco Salva, CEO of Azitra. "As a leading cancer site that treats thousands of patients a year, oncologists at MD Anderson understand the impact of EGFRi-associated rash, which impacts up to 80% of patients receiving EGFRi therapies. As this major side effect frequently leads to treatment interruptions or discontinuations, the field is in need of innovative solutions like ATR-04, a topically applied product with the potential to help patients stay on their primary cancer treatments. We're glad to be working with the committed staff at MD Anderson, our sixth clinical site, as we aim to accelerate the development of our ATR-04 program."

The multicenter, randomized, double-blind, vehicle-controlled Phase 1/2 clinical study (NCT06830863) is designed to evaluate the safety and tolerability of topical ATR04-484 for the treatment of EGFRi-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 early efficacy signals. The study is currently enrolling patients for Cohort 1, which is anticipated to enroll a total of eight patients.

About ATR04-484

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 to be safe by deleting an antibiotic resistance gene and engineering auxotrophy to control the growth of ATR04-484. Preclinical data have shown that ATR-04 can reduce levels of IL-36γ, a key pro-inflammatory cytokine elevated in these rashes. In addition, ATR-04 has also been shown to inhibit the growth of *S. aureus* in preclinical studies, which often colonizes the skin of affected patients. The FDA has granted Fast Track designation to ATR-04 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

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 adult Netherton syndrome patients. ATR-04, Azitra's additional advanced program, utilizes another engineered strain of *S. epidermidis* for the treatment of EGFR inhibitor ("EGFRi") 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 has an open IND for its ATR-04 program in patients with EGFRi associated rash. 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 (i) our results for the Phase 1b clinical trial for our ATR-12, (ii) the development for the Phase 1/2 clinical trial for our ATR-04 program and the initiation of dosing and anticipated enrollment in the Phase 1/2 clinical trial for our ATR-04 program, and (iii) statements about our clinical and preclinical programs, including ATR-01, 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: the timing of clinical trials and their results as we may experience delays in the provision of results for ATR-12 and/or ATR-04 or, if we do, that such data may not be favorably received; 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 on February 24, 2025. 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.
Jon Nugent
205-566-3026
jnugent@tiberend.com

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

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