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Azitra, Inc. Expands Eligibility for ATR-04 Phase 1/2 Clinical Trial to Include Patients with Rashes due to KRAS and MEK Inhibitors

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Expanded eligibility significantly broadens potential treatment opportunities for ATR-04 beyond EGFR inhibitor-associated skin rash

Additional protocol modifications expected to facilitate patient recruitment and accelerate clinical trial enrollment

BRANFORD, Conn., Oct. 29, 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 amendments to its ongoing Phase 1/2 clinical trial of ATR04-484 that significantly expand patient eligibility to include individuals with rash associated with KRAS and MEK inhibitors. The expanded eligibility also includes patients with neurofibromatosis type 1 (NF1) with rash associated with MEK inhibitors. The amendments also shorten the required washout periods for antibiotics and steroids. Together, these changes broaden the potential treatment opportunities for ATR-04 beyond its initial focus on epidermal growth factor receptor inhibitor (EGFR)-associated skin rash, while expanding the pool of eligible patients to facilitate recruitment.



The multicenter, randomized, double-blind, vehicle-controlled Phase 1/2 study ([NCT06830863](#)) is evaluating the safety, tolerability, bioavailability, pharmacodynamics, and preliminary efficacy of topical ATR04-484. The protocol amendments for the Phase 1/2 clinical trial follow Azitra's recent announcement that the study's safety review committee recommended proceeding to Cohort 2 following its review of available safety data from Cohort 1. Cohort 2 is expected to enroll approximately 24 patients who will receive once-daily treatment for 28 days.

KRAS inhibitors and MEK inhibitors are precision therapeutics used to treat various cancers, including non-small cell lung cancer (NSCLC), melanoma, colorectal cancer, and ovarian cancer. Combined, approximately 85,000 patients undergo KRAS or MEK inhibitor treatment in the United States annually. While these therapies have expanded treatment options for patients with cancer, dermatologic adverse effects, including skin rash, can substantially impair quality of life and may require dose reductions, treatment interruptions or discontinuation. The addition of these patients further broadens the potential clinical applications being explored for ATR-04 on top of the approximately 220,000 patients undergoing EGFRi treatment in the United States annually.

The expanded eligibility criteria include patients with NF1 with MEK inhibitor-associated rash. NF1 is a rare genetic disorder characterized by the development of tumors along nerves that affects approximately 100,000 patients in the United States.

"These expansions to the Phase 1/2 trial protocol represent a significant step for our ATR-04 program, increasing the possibility for this innovative treatment to benefit cancer and certain neurofibromatosis patients experiencing debilitating rash due to several targeted therapies," said Francisco Salva, Chief Executive Officer of Azitra. "While these therapies have transformed treatment for many patients, associated skin toxicities can significantly impact quality of life and interfere with treatment. By expanding our study to include patients with rash due to KRAS and MEK inhibitors, we are broadening the potential opportunity for ATR-04. Equally important, we believe the additional protocol modifications will facilitate patient recruitment and help accelerate enrollment. Following our recent advancement to Cohort 2, we are encouraged by the continued progress of this program and its potential to provide a new treatment option for patients affected by debilitating skin conditions."

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 skin rashes associated with various therapies for cancer treatment and neurofibromatosis. ATR04-484 was selected based on its preclinical profile of reducing the pro-inflammatory cytokine IL-36γ and *Staphylococcus aureus* levels, both of which are elevated in patients with cancer treatment-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. The U.S. Food and Drug Administration (the "FDA") has granted Fast Track designation to ATR04-484 for cancer treatment-associated rash, recognizing the high unmet medical need for up to 300,000 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 skin rashes associated with cancer and neurofibromatosis treatments. Azitra has received Fast Track designation from the FDA for cancer treatment-associated rash, which impacts up to 300,000 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 expected effects of the protocol amendments, including on patient recruitment and enrollment, (iii) the safety and preliminary efficacy data from the trial, (iv) the potential of ATR-04 to treat EGFRi-, KRASi-, MEKi- associated skin rash and other similar rashes, including its potential to be the first live biotherapeutic developed for this indication, (v) the size of the potential patient population and the potential benefits of Fast Track designation, and (vi) 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; the protocol amendments may not facilitate recruitment or accelerate enrollment as anticipated; 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 expanded patient populations may present different safety or efficacy profiles; 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.

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