Azitra, Inc. to Present ATR-04 Program Update at ASCO 2025

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Azitra is developing ATR04-484 for the treatment of EGFR inhibitor-associated rash with plans to dose first patient in Phase 1/2 trial in the first half of 2025

BRANFORD, Conn., April 25, 2025 /PRNewswire/ -- Azitra, Inc. (NYSE American: AZTR), a clinical stage biopharmaceutical company focused on developing innovative therapies for precision dermatology, today announced that an abstract detailing the Phase 1/2 clinical trial of ATR04-484 in EGFR inhibitor ("EGFRi")-associated rash has been accepted for presentation at the 2025 American Society of Clinical Oncology (ASCO) Annual Meeting being held May 30-June 3, 2025 in Chicago.

"We look forward to presenting an update on the ATR-04 program at ASCO as we plan to dose the first patient in the first half of 2025," said Francisco Salva, CEO of Azitra. "ASCO is widely regarded as the most prestigious cancer research conference in the world, and we are eager to educate leaders in the oncology community on the potential of ATR04-484 to treat the unique dermatologic toxicities that often accompany EGFRi treatments, which can hamper treatment efforts and cause significant physical and psychological discomfort for patients."

ATR04-484 is a live biotherapeutic product candidate including an isolated, naturally derived *Staphylococcus epidermidis* strain that was engineered to be safe by deleting an antibiotic resistance gene and engineering auxotrophy to control the growth of ATR04-484. ATR04-484 is in development for EGFRi-associated skin rash, which is associated with the suppression of skin immunity by EGFR inhibitors and subsequent inflammation, often accompanied by elevated levels of IL-36γ and *S. aureus*. Azitra has received Fast Track designation from the FDA for EGFRi associated rash and has initiated a Phase 1/2 clinical study in patients with EGFRi rash with the first patient expected to be dosed in the first half of 2025.

EGFR inhibitors are a class of cancer drugs that target and block the activity of the EGFR protein, which plays a crucial role in cell growth and survival. They are primarily used to treat certain types of cancer, including non-small cell lung cancer (NSCLC) and colorectal cancer.

The full ASCO abstracts will be available on May 22, 2025, after 5 p.m. ET. Abstract titles are available at: https://www.asco.org/abstracts.

About Azitra, Inc.

Azitra, Inc. is a clinical stage biopharmaceutical company focused on developing innovative therapies for precision dermatology. The Company'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 the abstract detailing the Phase 1/2 clinical trial for our ATR-04 program, the initiation of dosing in the Phase 1/2 clinical trial for our ATR-04 program, and statements about 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 fail to present this abstract detailing the Phase 1/2 clinical trial or, if we are able to do so, that the abstract will be favorably received; we may experience delays in the dosing the first patient in this Phase 1/2 trial; 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. Azitra explicitly disclaims any obligation to update any forward-looking statements except to the extent required by law.

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