Azitra Receives Fast Track Designation for ATR-04 for Skin Rash from EGFR Inhibitors

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BRANFORD, Conn.--(BUSINESS WIRE)--Sep. 18, 2024-- Azitra, Inc. (NYSE American: AZTR), a clinical-stage biopharmaceutical company focused on developing innovative therapies for precision dermatology, today announced the U.S. Food and Drug Administration (FDA) has granted Fast Track Designation for topically applied ATR-04 to treat moderate to severe Epidermal Growth Factor Receptor inhibitor (EGFRi) associated dermal toxicity.

Francisco Salva, Azitra's CEO, stated, "We are thrilled to announce the FDA has granted Fast Track designation to ATR-04, demonstrating that the FDA recognizes the unmet need for treatment of EGFRi-associated skin rash. Many cancer patients receive EGFR inhibitors, which often have significant side effects, resulting in rashes that require off-label treatment with antibiotics, steroids or other medications, or discontinuation of EGFRi therapy. The skin toxicity creates a high burden for these cancer patients, with a profound impact on their quality of life. We look forward to potentially accelerating the development of ATR-04 to treat this condition."

The FDA's Fast Track program aims to facilitate the development, and expedite the review, of novel potential therapies that are designed to treat serious conditions and have the potential to address significant, unmet medical needs. This may include more frequent meetings with the FDA and eligibility for accelerated approval or rolling review.

ATR-04 is a live biotherapeutic product candidate containing an isolated, naturally derived *Staphylococcus epidermidis* strain that was engineered to be safer by deleting an antibiotic resistance gene and engineering auxotrophy to control the growth of ATR-04. ATR-04 is in development for EGFRi-associated skin rash, which is caused by the suppression of skin immunity and subsequent inflammation and often elevated levels of IL-36γ and *S. aureus*. Approximately 150,000 patients are affected by EGFRi-induced skin toxicity in the United States, representing a >$1 billion market opportunity.

Azitra plans to initiate a multicenter, randomized, controlled Phase 1/2 clinical trial of ATR-04 in patients with dermal toxicity due to EGFR inhibitors by the end of 2024.

About Azitra, Inc.

Azitra, Inc. is an early-stage clinical biopharmaceutical company focused on developing innovative therapies for precision dermatology using engineered proteins and topical live biotherapeutic products. The Company has built a proprietary platform that includes a microbial library comprised of approximately 1,500 unique bacterial strains that can be screened for unique therapeutic characteristics. The platform is augmented by artificial intelligence and machine learning technology that analyzes, predicts and helps screen the Company's library of strains for drug like molecules. The Company's initial focus is on the development of genetically engineered strains of *Staphylococcus epidermidis*, or *S. epidermidis*, which the Company considers to be an optimal therapeutic candidate species for engineering of dermatologic therapies. 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 clinical development of our ATR-04 product candidate and the expected benefits of the FDA's grant of Fast Track designation for ATR-04.

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 not realize the potential benefits of the FDA's grant of Fast Track designation for ATR-04; we may fail to successfully complete our Phase 1/2 trial for ATR-04 and preclinical studies of other product candidates; we may not be able to obtain additional working capital with which to continue our current operations and clinical trials as and when needed; success in early phases of preclinical and clinical trials do not ensure later clinical trials will be successful; no drug product incorporating our engineered proteins or topical live biotherapeutic products has received FDA premarket approval or otherwise been incorporated into a commercial drug product; and those other risks disclosed or incorporated in the section "Risk Factors" included in our Form 10-Q filed with the SEC on August 12, 2024. Azitra explicitly disclaims any obligation to update any forward-looking statements except to the extent required by law.

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