Azitra Receives Study May Proceed letter from the FDA for IND to Treat Skin Rash from EGFR Inhibitors

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- New investigational new drug (IND) application cleared to proceed by the US FDA for a Phase 1/2 clinical study of ATR-04 for moderate to severe EGFR inhibitor (“EGFRi”) associated dermal toxicity.
- There are an estimated 150,000 patients with EGFRi-associated skin rash in the US, representing a >$1 billion global market size.
- Preclinical data show ATR-04 reduces IL-36γ and *Staphylococcus aureus*, key drivers of EGFRi-associated skin rash.

BRANFORD, Conn.--(BUSINESS WIRE)--Aug. 22, 2024-- Azitra, Inc. (NYSE American: AZTR), a clinical-stage biopharmaceutical company focused on developing innovative therapies for precision dermatology, today announced the clearance of an investigational new drug (IND) application to U.S. Food and Drug Administration (FDA) for a first-in-human Phase 1/2 clinical study of ATR-04 for moderate to severe EGFRi associated dermal toxicity.

Francisco Salva, Azitra’s CEO, stated, "We are delighted to announce a new IND clearance in an indication with high unmet need. Many cancer patients receive EGFR inhibitors, which are efficacious for certain cancers. However, these EGFR inhibitors often have significant side effects, resulting in rashes that require treatment with antibiotics, steroids or other medications. In some cases, discontinuation of cancer therapy with the EGFR inhibitors is necessary. There are no approved therapies for this skin toxicity, and it is a high burden for these cancer patients. We are excited to expand Azitra’s clinical pipeline with this IND.”

ATR-04 is a live biotherapeutic product candidate including 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 by EGFRis and subsequent inflammation and often elevated levels of IL-36γ and *S. aureus*. There are approximately 150,000 patients suffering from EGFRi-induced skin toxicity in the United States, representing a >$1 billion market opportunity.

Earlier this year, Azitra announced the preclinical data around ATR-04 at the Society for Investigative Dermatology (SID) annual meeting and the Annual Meeting for the American Society of Cell and Gene Therapy, showing significant reductions in IL-36γ and methicillin-resistant *S. aureus* (MRSA) in preclinical models.

Following the clearance of the IND, Azitra plans to initiate a multicenter, randomized, controlled Phase 1/2 clinical trial of ATR-04 in patients undergoing EGFR inhibitors with dermal toxicity 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 expected timing of the presentation of data from the Phase 1/2 study of ATR-04 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 successfully complete our Phase 1/2 trial for ATR-04 and preclinical studies of other product candidates and obtain required approval before commercialization; 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 are described 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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