Azitra, Inc. Announces Late-Breaking Presentation at the European Academy of Dermatology and Venereology Congress

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BRANFORD, Conn.--(BUSINESS WIRE)--Sep. 24, 2024-- Azitra, Inc. (NYSE American: AZTR), a clinical-stage biopharmaceutical company focused on developing innovative therapies for precision dermatology, today announced the upcoming late-breaking presentation related to ATR-04. The presentation by Dr. Mary Spellman will take place on Thursday, September 26, 2024, in a late-breaking oral session entitled "Development of a *Staphylococcus epidermidis* strain for the topical treatment of epidermal growth factor receptor (EGFR) inhibitor-induced dermal toxicity" at the European Academy of Dermatology and Venereology (EADV) Congress 2024 in Amsterdam.

ATR-04 is a live biotherapeutic product candidate consisting of an *S. epidermidis* strain that was isolated from a healthy volunteer and 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 toxicity, 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. Azitra has an active IND for a multicenter, randomized, controlled Phase 1/2 clinical trial of ATR-04 in patients with dermal toxicity due to EGFR inhibitors, and ATR-04 has received Fast Track designation from the FDA.

The data in the oral presentation will showcase the preclinical development of ATR-04 and details around the planned Phase 1/2 clinical trial in patients with dermal toxicity due to EGFR inhibitors.

The presentation will be available on Azitra's website at https://ir.azitrainc.com/news-events/presentations.

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 1b study of ATR-12, the filing of an IND application, and the presentation of data from our Phase 1b for ATR-04, the IND filing for ATR-01, the timing of having a signed license agreement with Bayer, and statements about our clinical and pre-clinical programs, and corporate and clinical/pre-clinical 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 concerning Azitra's programs and operations 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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