Azitra, Inc. Announces Positive Preclinical Data for ATR-01 Program, Designed to Treat Ichthyosis Vulgaris

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ATR-01, which uses a filaggrin-secreting strain of S. epidermidis, is in preclinical development for ichthyosis vulgaris

Preclinical data show production of active, functional filaggrin delivered through human stratum corneum and repair of damaged model skin

Further details to be presented in virtual presentation at BIO-Europe ®

BRANFORD, Conn., Oct. 20, 2025 /PRNewswire/ -- Azitra, Inc. (NYSE American: AZTR), a clinical stage biopharmaceutical company focused on developing innovative therapies for precision dermatology, today announced that Cofounder and Chief Operating Officer, Travis Whitfill, PhD, MPH, will present positive preclinical progress for its ATR-01 program, targeting the treatment of ichthyosis vulgaris, a disease caused by missing or abnormal filaggrin levels. The detailed data will be presented virtually to the BIO-Europe® conference, which is being held in Vienna, Austria, November 3-5, 2025.

The ATR-01 program utilizes a strain of *S. epidermidis* called ATR01-616. The strain has been engineered to secrete a functional unit of the human filaggrin protein. In the data being presented at BIO-Europe, ATR01-616 was found to have a positive pharmacology profile across multiple preclinical models. In *in vitro* models, ATR01-616 secreted functional filaggrin, as measured by keratin binding assays. Furthermore, in *ex vivo* human skin, it was found to deliver filaggrin through the stratum corneum, as was measured with fluorescence immunohistochemistry. In this model, ATR01-616 delivered filaggrin below the skin barrier ($p < 0.05$). Finally, in an *ex vivo* damaged pig skin model, ATR01-616 was shown to significantly reduce transepidermal water loss compared to vehicle control ($p < 0.002$). Together, these data demonstrate positive pharmacological activity and biodistribution.

"We're thrilled to announce positive preclinical data for our ATR-01 program during BIO-EUROPE as we advance towards a first-in-human clinical trial in ichthyosis vulgaris," said Francisco Salva, CEO of Azitra. "Ichthyosis vulgaris is an autosomal semidominant genetic disorder that impacts approximately 1.3 million in the U.S. who have no treatment options beyond symptom management. We are optimistic that this innovative, topically delivered treatment option has the potential to directly address the disease pathophysiology. We look forward to further updates on this program in 2026, including details around a path to first-in-human studies."

In addition to presenting the preclinical progress of ATR-01, Dr. Whitfill will also provide updates on Azitra's two clinical programs, ATR-12 and ATR-04. During the conference, Dr. Whitfill will also conduct one-on-one meetings with registered investors and potential partners.

About Azitra

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. Azitra is also progressing ATR-01, a preclinical program targeting ichthyosis vulgaris, with the goal of submitting an IND submission in 2026. The ATR-12, ATR-04 and ATR-01 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 future presentation of preclinical or clinical data for Azitra's product candidates, results of Azitra's preclinical studies of ATR01-616, the characteristics and efficacy of ATR01-616, progress of Azitra's product development activities and preclinical and clinical trials, and expectations regarding the safety and effectiveness of Azitra's product candidates.

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, those inherent in research and development, including uncertainties related to ongoing and planned clinical trials and preclinical studies, review and approvals by regulatory authorities of Azitra's product candidates, Azitra's reliance on third parties to manufacture product candidates, and Azitra's continued ability to fund its development programs. 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, and subsequent reports filed with the SEC. Azitra explicitly disclaims any obligation to update any forward-looking statements except to the extent required by law.

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