Azitra, Inc. Announces Positive Preclinical Data of ATR-12 and Clinical Design in Netherton Syndrome Presented at the ASGCT Annual Meeting

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- ATR-12 has nanomolar inhibition of key protease in vitro that drives Netherton syndrome
- Topical application of ATR-12 to ex vivo human skin results in superior LEKTI delivery compared to topical LEKTI application
- ATR-12 reduces IL-36γ, a pro-inflammatory cytokine that drives Netherton syndrome
- Safe and well tolerated in minipigs

BRAINTFORD, Conn.--(BUSINESS WIRE)--May 10, 2024--Azitra, Inc. (NYSExchange:AZTR), a clinical-stage biopharmaceutical company focused on developing innovative therapies for precision dermatology, today announced preclinical data from the Company’s platform and pipeline. The data are being presented on Friday, May 10, 2024, in two oral presentations entitled “Engineered Staphylococcus Epidermidis as a Protein-Delivery System for Treating Skin Diseases” and “Engineered Staphylococcus epidermidis Strain Expressing LEKTI-D6 (ATR12-351) for Netherton Syndrome” at the American Society of Gene and Cell Therapy (ASGCT) 2024 Annual Meeting in Baltimore, MD.

The data in the two oral presentations today showcase the preclinical development of ATR-12 and the clinical study design of a Phase Ib study in Netherton syndrome patients. In vitro data show that LEKTI (lympho-epithelial Kazal-type-related inhibitor) protein secreted by ATR-12 has nanomolar inhibition of a key protease that drives Netherton syndrome, kallikrein (KLK) 5 ([Cγ2]+K43K46K51) 63. Additionally, in human ex vivo Netherton syndrome models, ATR-12 supersedes reductions protease activity nearly 7-fold to levels comparable to healthy skin. Furthermore, in vivo human skin models, ATR-12 led to a higher amount of LEKTI delivery to the skin compared to topically applied LEKTI alone (0.1 µg/cm2 vs. 3.3 µg/cm2, p=0.008) after 24 hours and resulted in deeper biodistribution of LEKTI. Application of ATR-12 in human skin cell culture reduced IL-36γ by 50% compared to skin extracts induced to overexpress IL-36γ. Topical application of ATR-12 in ex vivo human skin treated with extrinsic reduced IL-36γ by 60%.

In studies conducted in minipigs with allogenic skin, topical application of ATR-12 resulted in 11.9 ng/mg2 of LEKTI on the surface of the skin vs. 2.6 ng/mg2 in the vehicle group at day 14. ATR-12 application was safe and well-tolerated in GTO toxicology studies with minipigs.

The oral presentation entitled “Engineered Staphylococcus epidermidis Strain Expressing LEKTI-D6 (ATR-12) for Netherton Syndrome” also provides the study design for an active clinical trial of ATR-12 in Netherton syndrome patients. The Phase Ib study (NCT06137157) is a multicenter, randomized, double-blind, vehicle-controlled study in adults ≥12 years with Netherton syndrome. Patients will be treated twice daily with 10 mg/mL ATR-12 for 14 days. The primary objective is to assess the safety and tolerability of topical application of ATR-12, and the secondary objectives are to evaluate efficacy signals (e.g., investigator and patient global assessments) and to evaluate the skin pharmacokinetics of LEKTI. Exploratory objectives include the evaluation of pharmacodynamic parameters, including and IL-36γ response, cytokine responses, biomarkers such as IL18, IL36, IL17, IL33, IL36γ, and chymotrypsin-like activity.

“We are thrilled to announce full preclinical data around ATR-12 as well as our clinical plan in Netherton syndrome that demonstrate proof-of-concept data supporting the use of genetically engineered skin commensals to deliver proteins to the skin,” said Travis Whitehill, Azitra’s co-founder and CEO.

“These data show the robust preclinical activity of ATR-12 in Netherton syndrome models and further supports the rationale behind our Phase 1b clinical trial in Netherton syndrome patients.”

The presentations are now available on Azitra’s website at https://ir.azitrainc.com/news-events/presentations.

About ATR-12

ATR-12 (also known as ATR12-351) is an engineered strain of S. epidermidis that expresses a fragment of human lympho-epithelial Kazal-type-related inhibitor (LEKTI), which is missing in patients with Netherton syndrome, a chronic and sometimes fatal disease of the skin estimated to affect approximately one in 10,000 newborns. ATR-12 has been engineered to deliver missing LEKTI protein when applied topically to Netherton syndrome patients. Azitra has an open IND for a Phase Ia clinical trial in adult patients (NCT05519017). Azitra has secured clinical sites and identified Netherton syndrome patients for enrollment in the Phase Ia trial. Phase Ib clinical trial, which will assess safety, tolerability, and efficacy endpoints. Azitra expects to announce initial safety data before year end.

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. This platform is supported 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://ir.azitrainc.com/news-events/presentations.

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 Ib study of ATR-12, the filing of an IND application, and the presentation of data from our Phase Ib for ATR-04, the IND filing for ATR-01, the timing of having a safe and effective product, the target patient population for our clinical trials, the potential impact of our product candidates on clinical outcomes for the patient population, and our ability to enroll patients in our clinical trials.

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 be able to successfully complete our Phase Ib trial for ATR-12 and pre-clinical studies of other product candidates and obtain required approval before commercialization; our product candidates may not be as effective, have less severe side effects or may be less expensive, may not be able to gain regulatory approval, or may be more expensive or less effective than competitive products or may not achieve or maintain market acceptance; our product candidates may fail to achieve clinical endpoints or may have severe or unexpected side effects; we may not be able to maintain or enter into commercial partnerships or enter into commercial partnerships that generate revenue at the levels required or provide access to necessary products or technologies; we may not be able to complete any of our funded clinical trials or achieve other milestone payments; we may not be able to attract sufficient funding from any collaborations; the impact of the COVID-19 pandemic on our business, results of operations, and cash resources; and other risks and uncertainties described in our Annual Report on Form 10-K filed with the SEC on March 15, 2024. Azitra explicitly disclaims any obligation to update any forward-looking statements except to the extent required by law.

Source: Azitra, Inc.