

Issuer Free Writing Prospectus  
Filed Pursuant to Rule 433  
Registration No. 333-280806  
July 15, 2024



**CORPORATE PRESENTATION**  
July 2024

**Precision dermatology powered by synthetic biology.**

## SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This document contains forward-looking statements concerning Azitra, Inc. (“Azitra”, the “Company,” “we,” “us,” and “our”). The words “believe,” “may,” “will,” “potentially,” “estimate,” “continue,” “anticipate,” “intend,” “could,” “would,” “project,” “plan,” “expect” and similar expressions that convey uncertainty of future events or outcomes are intended to identify forward- looking statements. These forward-looking statements include, but are not limited to, statements concerning the following:

- our future financial and operating results;
- our intentions, expectations and beliefs regarding anticipated growth, market penetration and trends in our business; the timing and success of our plan of commercialization;
- our ability to successfully develop and clinically test our product candidates;
- and the adequacy of the net proceeds of this offering.

These forward-looking statements are subject to a number of risks, uncertainties and assumptions, including (i) we are an early-stage clinical biopharmaceutical company with limited operating history, (ii) there are no drug products to date that incorporate our microbial library and genetic engineering platform and the clinical and commercial utility of our microbial library and genetic engineering platform is uncertain and may never be realized; (iii) we have only recently commenced Phase 1 clinical studies of our initial product candidates and our product candidates will require extensive additional preclinical and clinical testing; (iv) we expect we will need additional financing to execute our business plan and fund operations, which additional financing may not be available on reasonable terms or at all; and (v) those other risks described or incorporated by reference in the “Risk Factors” section of the prospectus dated July 15, 2024 (“Prospectus”) filed by Azitra with the Securities and Exchange Commission on July 15, 2024.

In light of these risks, uncertainties and assumptions, the forward-looking events and circumstances discussed in this document may not occur and actual results could differ materially and adversely from those anticipated or implied in our forward-looking statements. You should not rely upon forward-looking statements as predictions of future events. Although we believe that the expectations reflected in our forward-looking statements are reasonable, we cannot guarantee that the future results, levels of activity, performance or events and circumstances described in the forward-looking statements will be achieved or occur. Azitra does not undertake and specifically disclaims any obligation to update or revise our forward-looking statements to reflect new circumstances or unanticipated events as they occur, except as required by law.

This document contains only basic information concerning Azitra. Because it is a summary it does not contain all of the information you should consider with regard to Azitra. You should read the Prospectus for more complete information about Azitra.

## Free Writing Prospectus

This presentation highlights basic information about us and the proposed offering. Because it is a summary, it does not contain all of the information that you should consider before investing. We have filed a registration statement (including a prospectus) with the SEC for the offering to which this presentation relates. The registration statement has not yet become effective. Before you invest, you should read the prospectus in the registration statement (including the risk factors described therein) and other documents we have filed with the SEC for more complete information about us and the offering.

You may access these documents for free by visiting EDGAR on the SEC Web site at <http://www.sec.gov>. Alternatively, we or any underwriter participating in the offering will arrange to send you the prospectus if you contact Maxim Group LLC, Prospectus Department, 405 Lexington Ave., New York, NY, 10174; Telephone: (212)-895-3745; Email: [syndicate@maximgrp.com](mailto:syndicate@maximgrp.com).

This presentation shall not constitute an offer to sell, or the solicitation of an offer to buy, nor will there be any sale of these securities in any state or other jurisdiction in which such offer, solicitation or sale would be unlawful prior to the registration or qualification under the securities laws of such state or jurisdiction. The offering will only be made by means of a prospectus pursuant to a registration statement that is filed with the SEC after such registration statement becomes effective.

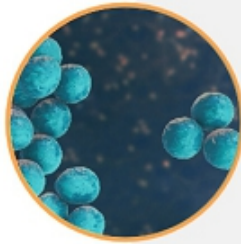
## Offering summary

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<b>Issuer:</b>	Azitra, Inc.
<b>Symbol:</b>	NYSE American: AZTR
<b>Offering Type:</b>	Best Efforts S-1 Follow-On
<b>Expected Offering Size:</b>	Up to \$10,000,000
<b>Securities Offered:</b>	<ul style="list-style-type: none"><li>• One share of Common Stock (or one Pre-Funded Warrant in lieu thereof), and two Class A warrants, each to purchase one share of Common stock</li></ul>
<b>Use of Proceeds:</b>	<ul style="list-style-type: none"><li>• Working capital and other general corporate purposes</li></ul>
<b>Sole Placement Agent:</b>	Maxim Group LLC

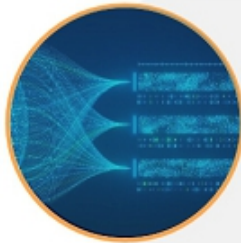
# Three foundational platforms for precision dermatology

POWERED BY SYNTHETIC BIOLOGY AND THE METAGENOME



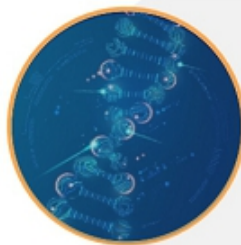
## Bacterial Cell Library

- Proprietary, robust library of **~1,500 microbial strains**
- Engineered and non-engineered bacterial chasses
- Over 60 species in house, mostly *Staphylococcus epidermidis*



## Artificial Intelligence / Machine Learning Discovery

- Predictive algorithms for **novel microbial-derived proteins, peptides & small molecules**
  - Exclusive agreement covering specific strains with team from Carnegie Mellon
  - Based on genetic sequences and biosynthetic gene clusters

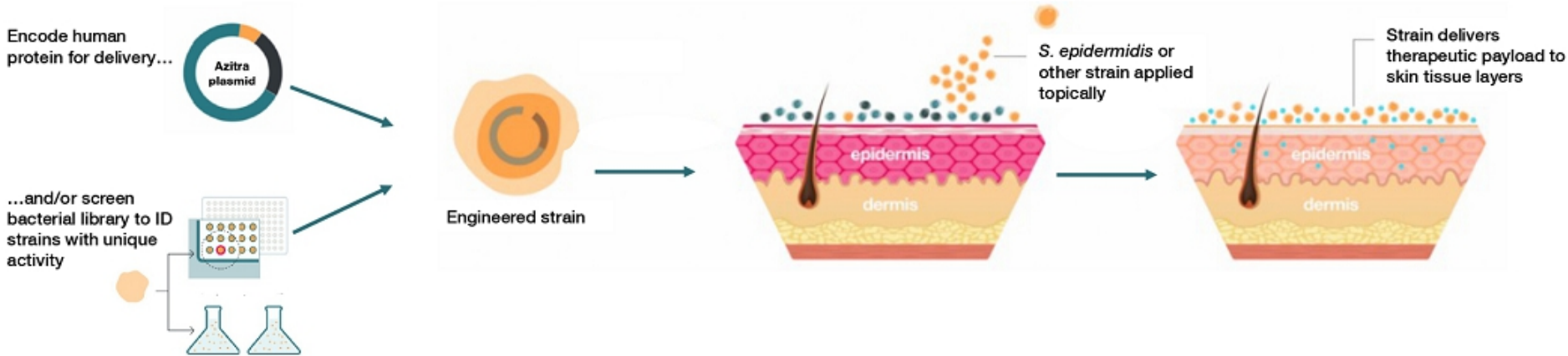


## Microbial Genetic Engineering Platform

- Demonstrated ability to make **novel transformations** to overcome challenge of thick cell walls and restriction modification systems
  - Exclusive worldwide license with Fred Hutchinson Cancer Center

# Using synthetic biology and *S. epidermidis* biology for skin therapeutics

- 1 Identify human or bacterial protein or molecule of interest
- 2 Engineer auxotrophy to control strain growth
- 3 Colonize affected skin with engineered strain
- 4 Secrete active molecule throughout layers of the epidermis for therapeutic treatment



# Differentiated approach in an attractive space

## Azitra's differentiated approach to precision dermatology

	Penetrates or delivers to skin	Disease modifying	Safe	Low cost	Ease of use
Oral small molecules	-	✗	-	✓	✓
Topical small molecules	✓	✗	-	✓	✓
Injectable antibodies	-	-	-	✗	✗
Topical gene therapy	-	✓	✓	✗	✓
Other gene therapies	✓	✓	-	✗	✗
 azitra™	✓	✓	✓	✓	✓

## Recent acquisitions in dermatology indicate interest in the sector<sup>1</sup>

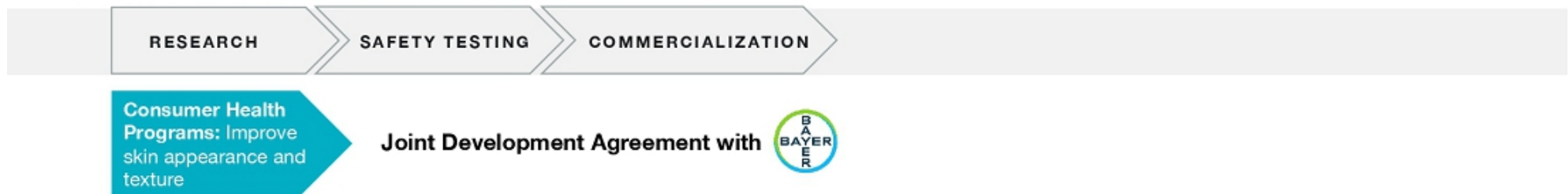
- ✓ 31 M&A deals announced or completed in medical dermatology from January 2020 – July 2024
- ✓ \$12.2 billion total
- ✓ Median deal size: \$50 million
- ✓ Mean deal size: \$393 million

# Azitra's pipeline features multiple internally developed programs


## FDA-regulated candidates for drug development



## Consumer/Cosmetic Product Development







ATR-12 Program

# Netherton Syndrome

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# ATR-12: LEKTI-Secreting *Staphylococcus epidermidis* for Netherton syndrome

## ATR-12 Summary

- **Netherton syndrome** is a rare, orphan autosomal recessive disease with no current FDA-approved treatment option
- Characterized by severe inflammation, pruritus, scaling, red, and dehydrated skin
  - Caused by mutations in the *SPINK5* gene, which encodes the serine protease inhibitor, **LEKTI** (lympho-epithelial Kazal-type related inhibitor)
  - Results in overactive proteases causing desquamation, skin barrier defects, and activation of inflammation
  - ~10% mortality rate in infants<sup>1</sup>
- **Mechanism of action:** Auxotrophic ATR-12 inhibits the overactive proteases through LEKTI fragment secretion
- **Pediatric Rare Disease Designation** received from FDA

## ATR-12 Key Facts



### Primary Mechanism:

Topical protein replacement and kallikrein Inhibition



### Clinical Status:

Phase 1b



### Global Prevalence:

~20K+ Patients<sup>2</sup>



### Peak Sales Opportunity:

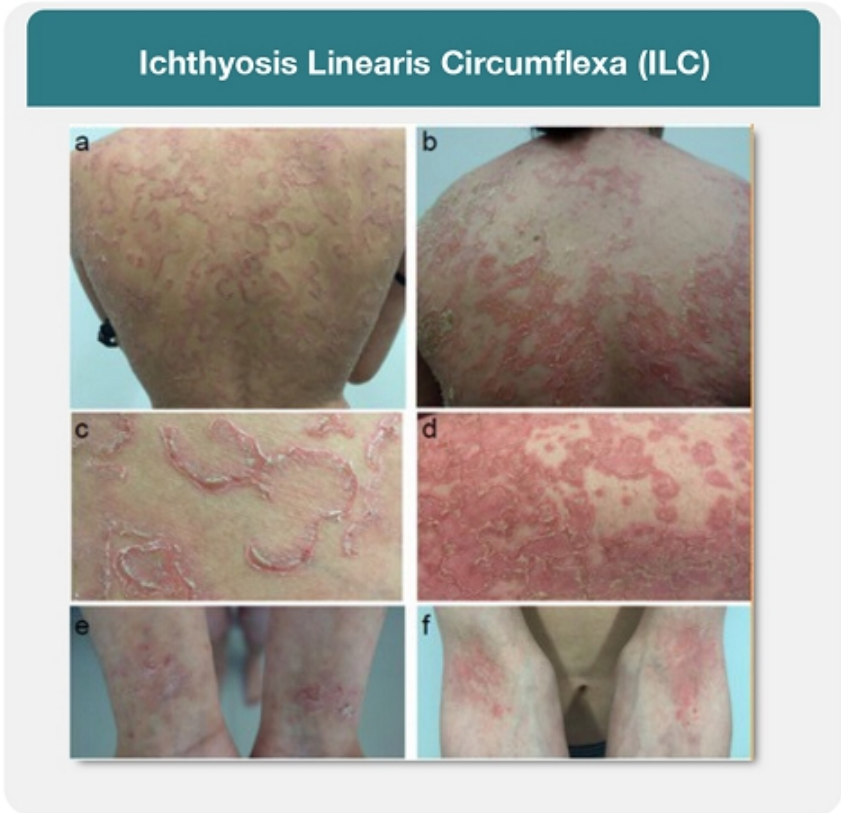
~\$250M<sup>3</sup>

<sup>1</sup> Bellon N et al. Br J Dermatol. 2021.

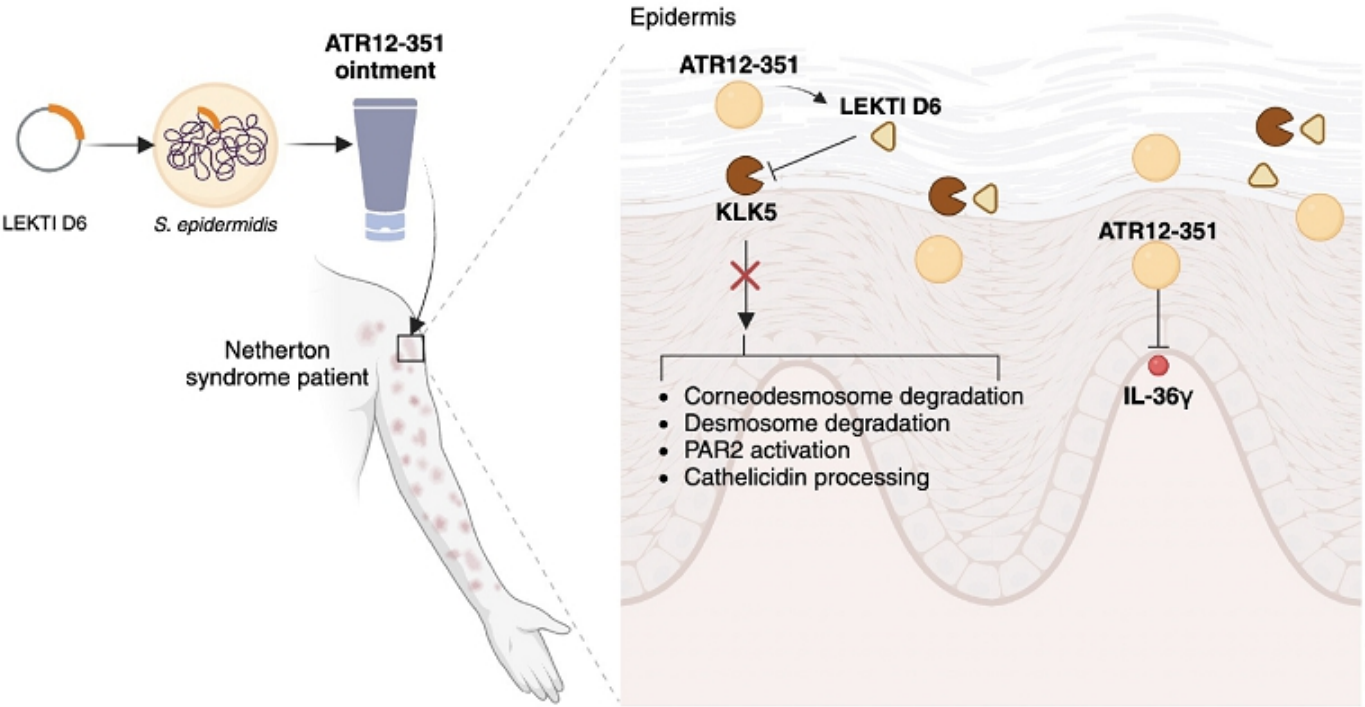
<sup>2</sup> Barbati F, et al. Front Pediatr. 2021.

<sup>3</sup> Company estimates of 2,500 patients x \$100,000 annually.

# Protein replacement strategy addresses multiple Netherton syndrome phenotypes



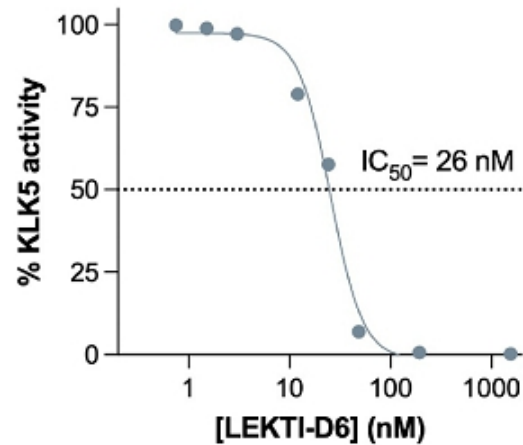
# Mechanism of action of ATR-12



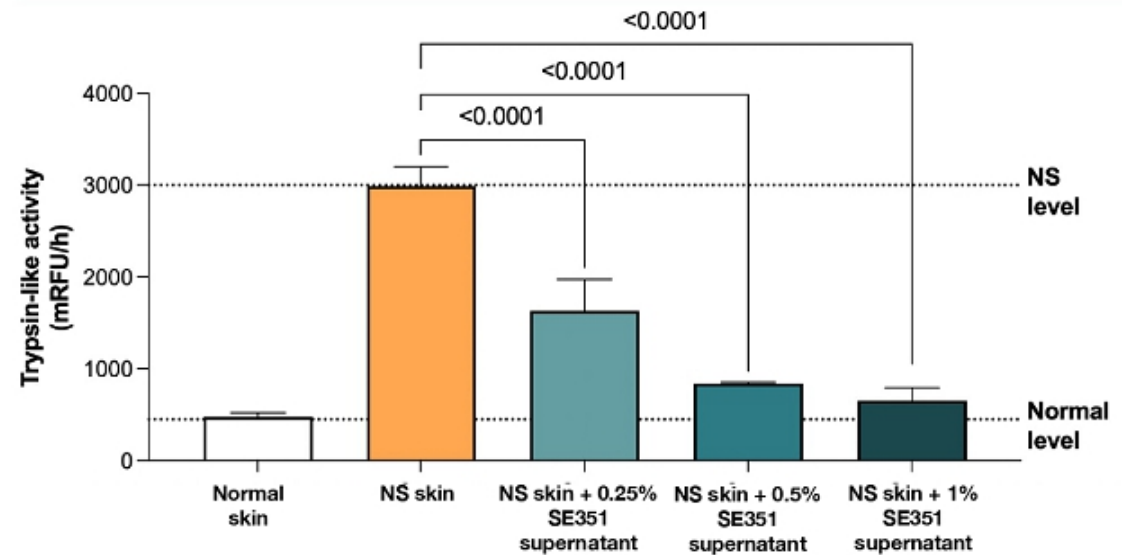
Collectively, ATR-12 addresses Netherton syndrome by LEKTI replacement and IL-36 $\gamma$  inhibition

# ATR-12 shows potent reduction in protease activity

Nanomolar IC<sub>50</sub> of KLK5 from SE351 *in vitro*

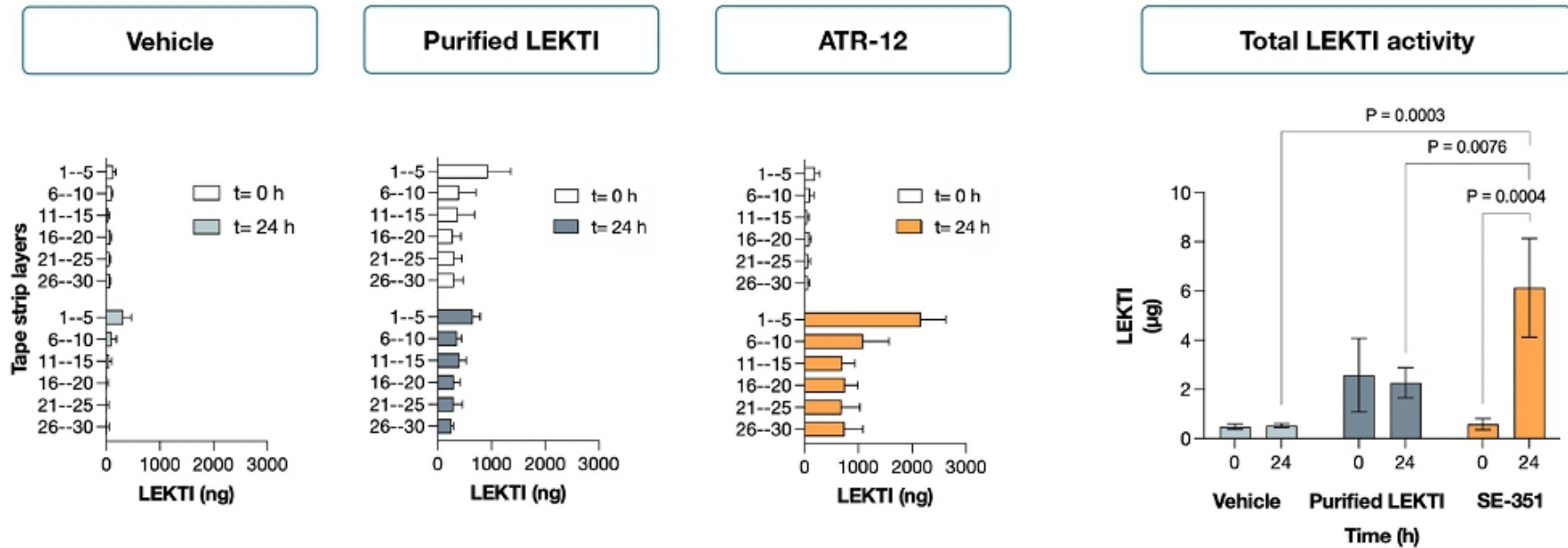


*S. epidermidis* strain SE351 (LEKTI-secreting) spent broth inhibition of human skin tape stripped extracts



- ✓ Nanomolar inhibition of KLK5
- ✓ Trypsin-like activity (key measure of protease activity in NS patients) decreased after addition of spent broth from LEKTI-secreting strain SE351 in ATR-12
- ✓ Dose-dependent response seen across concentrations of supernatant

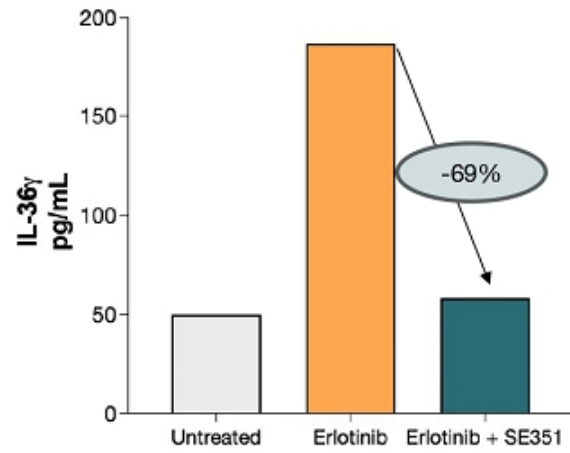
# Penetration of LEKTI-like activity into *ex vivo* human skin



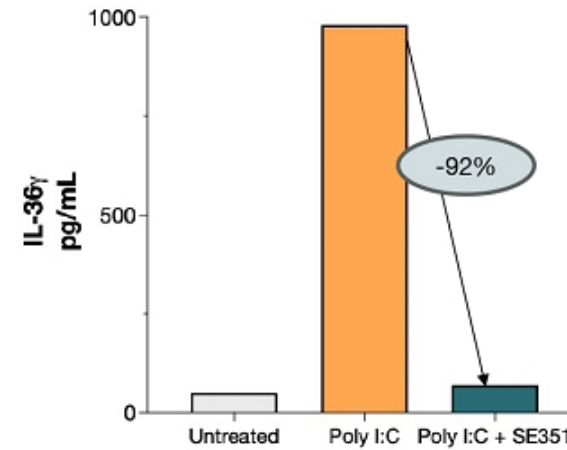
- ✓ LEKTI delivery is significantly higher after 24 hours compared to T0 in all layers following ATR-12 application
- ✓ The LEKTI activity penetrates to at least 30 layers deep in substantial amounts with µg of protein delivered after 24 hours
- ✓ LEKTI delivery by ATR-12 is superior compared to topical protein delivery alone

# ATR-12 decreases IL-36 $\gamma$ levels

Reconstructed epidermis induced with erlotinib and treated with SE351 cells



HaCaT cells induced with Poly I:C and treated with SE351 cell-free supernatant



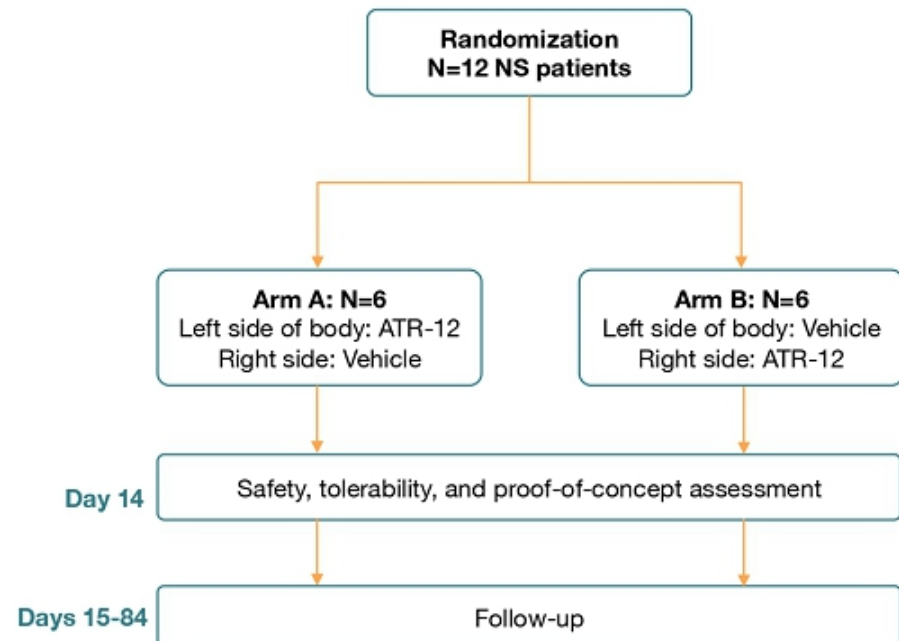
- ✓ ATR-12 cells and supernatant reduce IL-36 $\gamma$ , a key pro-inflammatory cytokine involved in NS inflammation, in multiple *in vitro* models

# Phase 1 clinical trial design

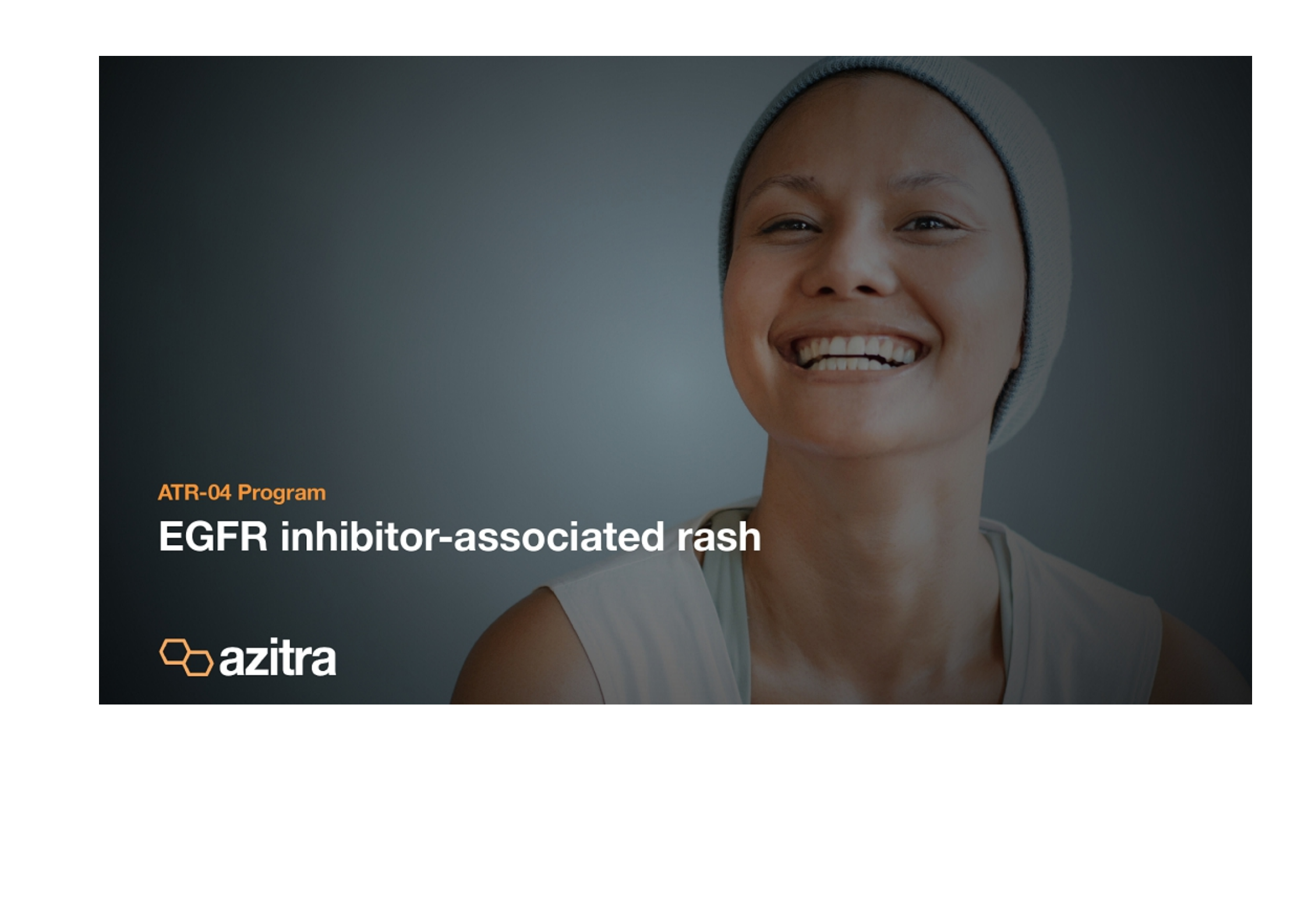
## Study overview

- Multicenter, randomized, double-blind, vehicle-controlled study in adults (n=12) with Netherton syndrome
  - Dose level:  $10^9$  CFU / g ATR-12
  - N=12 patients dosed twice daily for 14 days
- Primary objective: to assess the safety and tolerability of topical application of ATR-12
- Secondary objectives:
  - Evaluate efficacy signals (investigator and patient global assessments, NS-modified SCORAD)
  - Evaluate the skin pharmacokinetics of rhLEKTI-D6
- Exploratory objectives:
  - Evaluate pharmacodynamic parameters, including anti-rhLEKTI response, cytokine responses, biomarkers such as KLK5, KLK7, IL-36 $\gamma$ , TARC/CCL17, trypsin-like activity, and chymotrypsin-like activity

## Design







ATR-04 Program

# EGFR inhibitor-associated rash

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# ATR-04: auxotrophic *S. epidermidis* for EGFR inhibitor-associated rash

## ATR-04 Summary

- Chemotherapy agents such as EGFR inhibitors and immunotherapies such as early BTK inhibitors lead to an aggressive and debilitating rash on most patients
- Severity of the rash is linked to IL-36 $\gamma$  signaling as well as correlations to *S. aureus* increases
- EGFR inhibitors produce the most prevalent and most predictable affliction
- **ATR-04** is topically administered and inhibits IL-36 $\gamma$  and *S. aureus*

## ATR-04 Key Facts



### Primary Mechanism:

Topical IL36 $\gamma$  inhibition, *S. aureus* control



### Clinical Status:

IND filing expected mid-2024



### US Prevalence:

~150,000 patients<sup>1</sup>



### Peak Sales Opportunity:

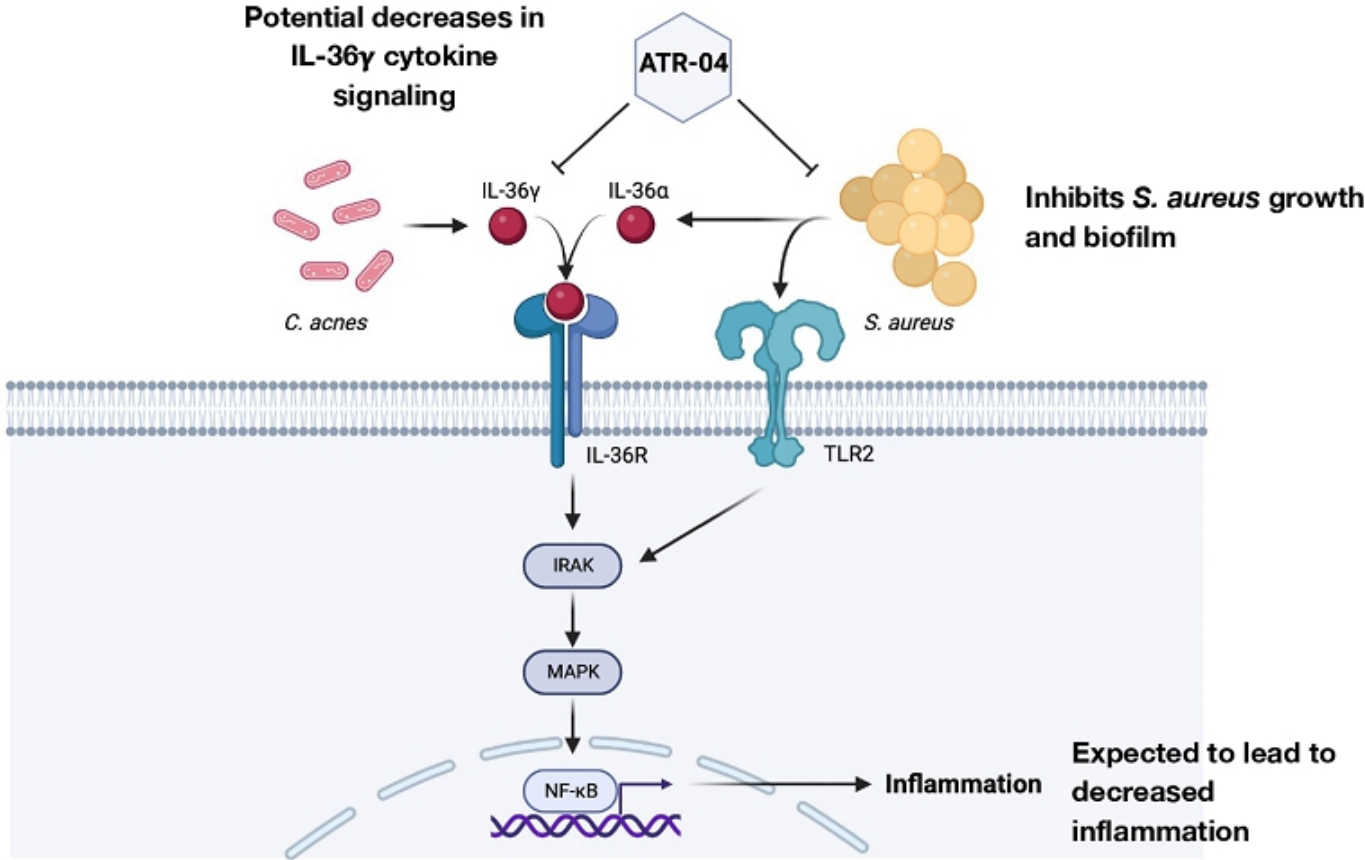
>\$1B<sup>2</sup>

# EGFRi-driven rash is highly prevalent with significant clinical impact



- Rash severity often linked to cancer drug dosing and correlates with *S. aureus* levels on the skin
- Rash can lead to significant changes in course of therapy and QOL
- **As many as 15-20% discontinue EGFRi therapy due to skin rash**

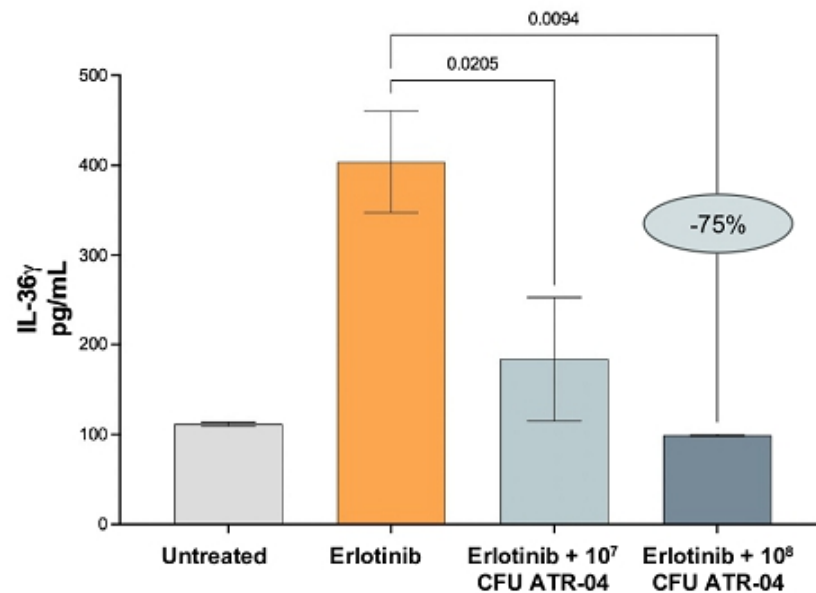
# Mechanism of action of ATR-04



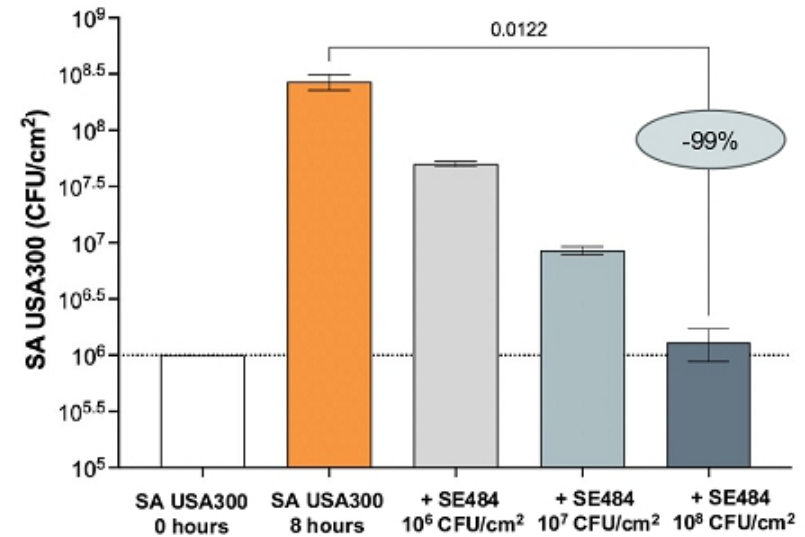
Collectively, ATR-04 addresses rash severity driven by EGFR inhibition

# In vitro data show ATR-04 reduces erlotinib-induced IL-36 $\gamma$ and *S. aureus*

IL-36 $\gamma$  reduction in reconstructed human epidermis



*S. aureus* reduction on ex vivo pig skin



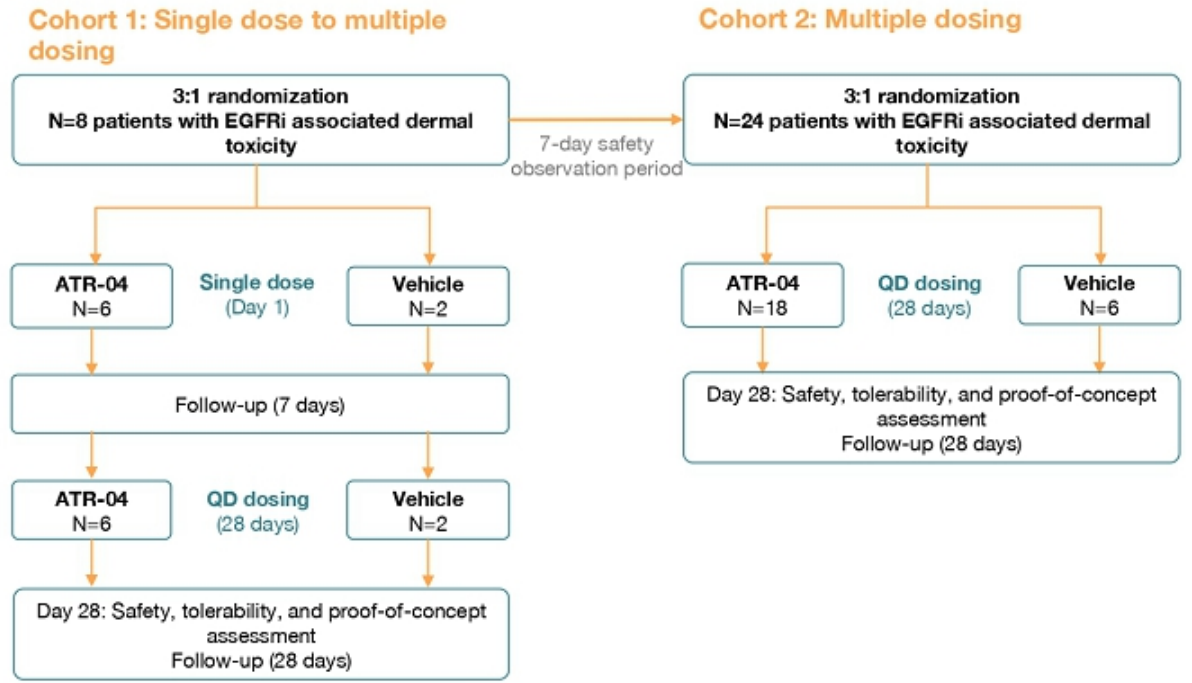
- ✓ IL-36 $\gamma$  is elevated in reconstructed human epidermis following erlotinib exposure
- ✓ ATR-04 reduces IL-36 $\gamma$  induced by erlotinib and reduces *S. aureus*
- ✓ Dose-dependent effect observed

# Phase 1/2 clinical trial design: IND submission summer 2024

## Study overview


- Multicenter, randomized, double-blind, vehicle-controlled study in adults (n=32) with EGFRi associated dermal toxicity
  - Dose level:  $10^9$  CFU / g ATR-04
  - Cohort 1 (n=8): single dose leading to multiple dose for 28 days
  - Cohort 2 (n=24): multiple dose cohort for 28 days
- Primary objective: to assess the safety and tolerability of topical application of ATR-04
- Secondary objectives:
  - Evaluate efficacy signals (modified CTCAE, pruritus, and pain)
  - Bioavailability of ATR-04
- Exploratory objectives:
  - Evaluate PD parameters, including IL-36 $\gamma$
  - Quality of life questionnaire

## Design

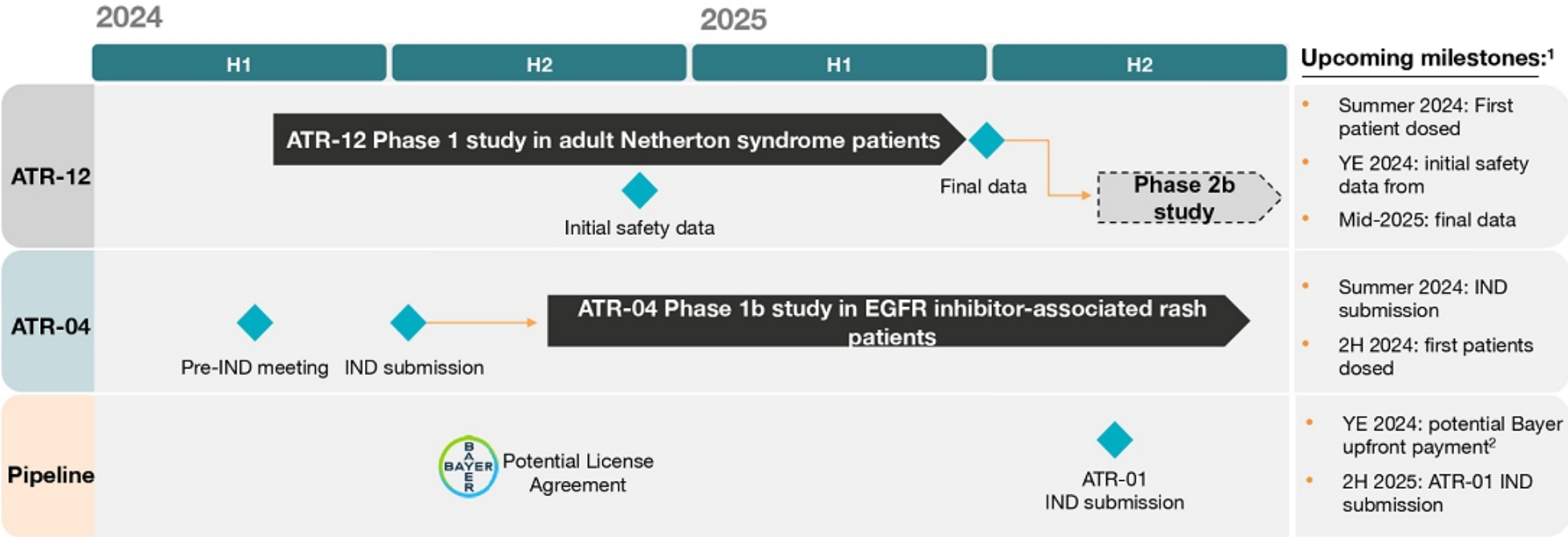


A woman with long dark hair, wearing a white lab coat and blue nitrile gloves, is focused on her work in a laboratory. She is using a pipette to transfer liquid into a small vial. The background is filled with various pieces of laboratory equipment, including a pipette rack, a scale, and other instruments, all slightly out of focus. The lighting is soft and professional, highlighting the scientist's concentration.

## Future Directions

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# ATR-12 and ATR-04 bring value-creating milestones in 2024-2025



<sup>1</sup> Upcoming milestones are estimates.  
<sup>2</sup> Please see Azitra's latest S-1 for risk factors related to the Bayer Agreement.



# Robust intellectual property with key patents issued

5 issued US patents

14 pending US patent applications

58 pending international patent applications



**2038**  
\*Treating skin disease with recombinant organisms

*\*Issued*



**2038**  
Treatment of skin disease with recombinant commensal skin microorganisms

*Pending*



**2038**  
\*Auxotrophic strains of Staphylococcus bacteria

*\*Issued*



**2038**  
Filaggrin subunits for treatment of eczema and ichthyosis vulgaris

*\*Issued*



**2039**  
LEKTI for Pruritis, Pain, Inflammation

*Pending*



Formulations for stabilizing microbiome products

*Pending*



**2034**  
\*Treating atopic dermatitis with recombinant organisms

*\*Issued*



**2038**  
Treating inflammatory skin disease with recombinant organisms

*Pending*



**2038**  
Commensal bacteria to treat cancer associated rash

*Pending*



**2038**  
Cosmetic compositions with engineered bacteria

*Pending*



**2038**  
Treatment of Netherton syndrome with LEKTI expressing microbes

*Pending*



**2039**  
LEKTI for treating skin cancer

*Pending*

## Capitalization table

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	As of June 30, 2024
Common Shares	960,146
Warrants (WAEP: \$54.00)	33,013
Options (WAEP: \$40.70)	41,608
Fully Diluted Shares Outstanding:	1,034,767

# Azitra is led by world-class management team



**Francisco Salva, MSc.**  
President and CEO

- Prior Co-Founder and VP of Operations at Acerta Pharma – Sold for \$6.3 billion
- Formerly Senior Director –Corporate Development at Pharmacyclics
- 25+ years experience in life science venture capital, investment banking and operating roles



**Travis Whitfill, M.P.H.**  
Co-Founder and COO

- Prior Partner at Bios Partners, a venture capital fund with \$350M+ assets under management
- Assistant Professor Adjunct in the Department of Pediatrics at Yale University
- Named one of Forbes' 30 Under 30 in healthcare in 2018



**Norman Staskey, CPA**  
CFO

- Currently Acting CFO via Danforth Advisors
- Previously, Managing Director E&Y
- 20+ years accounting experience, including multiple IPO, SPAC and M&A transactions



**Mary Spellman, M.D.**  
Acting CMO

- Prior CMO of Revance Therapeutics, Menlo Therapeutics, and Castle Creek Biosciences
- Previously Scientific Director at Biogen and Novartis
- 30+ years of dermatology and broad industry experience, including 10+ NDAs



**Leonard Milstone, M.D.**  
Professor Emeritus of Dermatology  
Yale School of Medicine  
Azitra Scientific Advisory Board

- Led the group that first demonstrated gene editing in the epidermis
- Discovered the unique proteoglycan Epican as well as keratins 4 and 13
- Former Chair, Medical and Scientific Advisory Board, Foundation for Ichthyosis and Related Skin Types



# Investment Highlights

## Azitra well-positioned to take advantage of synthetic biology innovations



### Established platforms for precision dermatology

- ✓ Poised to generate clinical patient data with 1<sup>st</sup> IND cleared and 2<sup>nd</sup> IND filing on way
- ✓ Established manufacturing and formulation systems
- ✓ Orphan dermatology indications



### Partnerships to expand the pipeline

- ✓ Key collaboration with top-tier consumer health corporation, Bayer
- ✓ Partnerships with top-tier academic institutions



### Strong business foundation

- ✓ \$52 million invested to date, including Bayer
- ✓ Comprehensive intellectual property
- ✓ Management team with history of multiple approved drugs and successful exits
- ✓ Multiple shots on goal for 2024-2025



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**THANK YOU**

Precision dermatology powered by synthetic biology.

A woman with long dark hair, wearing a white lab coat and blue nitrile gloves, is focused on her work in a laboratory. She is using a pipette to transfer liquid into a small vial. The background is filled with various pieces of laboratory equipment, including a pipette rack, a scale, and other instruments, all slightly out of focus. The lighting is soft and professional, highlighting the scientist's concentration.

**APPENDIX**

 **azitra**

# Bayer consumer health product joint development partnership



- ✓ Long-established expertise in dermatology and consumer skin health
  - ✓ Global brand recognition
- ✓ Formulation, marketing and regulatory expertise












- ✓ Deep expertise, broadly applicable platform, and 1,500+ proprietary *S. epidermidis* strains
- ✓ Translational leader in dermatology and *S. epidermidis* biology
  - ✓ Key academic and clinical collaborator network

**Build a leading, world-class consumer care product line**

## Joint Development Agreement overview:

- ✓ Joint development on *S. epidermidis* strains and products for eczema-prone skin
- ✓ Azitra is responsible for early research, and Bayer is responsible for clinical development and commercialization

# ATR-12 is a differentiated approach for Netherton syndrome







	Company	Asset	Description	Status	Topical treatment	Protein replacement	Disease Modifying
Kallikrein inhibitors	 azitra™	ATR-12	<i>S. epidermidis</i> strain expressing LEKTI; topical	Phase 1	✓	✓	✓
	SIXERA PHARMA	SXR1096	KLK inhibitor; topical	Phase 1 (EU)	✓	✗	–
	 biocryst*	BCX17725	LEKTI-2 variant.FC; subcutaneous injection	Preclinical	✗	✓	✓
Gene therapy	 MoST	BBP-561	KLK5/7 inhibitor; topical	Preclinical	✓	✗	–
	 Krystal	KB104	Gene therapy; topical	Preclinical	✓	✗	✓
	 Daiichi-Sankyo	DS-2324a	Gene therapy; IV/subcutaneous injection	Phase 1 (EU)	✓	✗	✓
Other	 QUOIN	QRX-003	Protease inhibitor; topical	Phase 2/3	✓	✗	–
	 Boehringer Ingelheim	Spesolimab	IL-36R antibody; injection	Phase 2	✗	✗	–
	 AnaptysBio	ANB019 <sup>1</sup>	IL-36R antibody; injection	Phase 2	✗	✗	–
	 MatriSys	MSB-6005	Skin microbiome therapy; topical	Preclinical	✓	✗	✗
	Investigator- initiated trial	Cosentyx <sup>1</sup>	IL-17A antibody; subcutaneous injection	Phase 2	✗	✗	✗



<sup>1</sup> Under investigation for broader category of ichthyoses.



## ATR-04 is a differentiated approach for EGFRi-related skin toxicities

	Company	Asset	Description	Status	Topical treatment	Disease modifying	IL-36γ targeted	Notes
US-based	 azitra	ATR-04	Epidermin-secreting <i>S. epidermidis</i> auxotrophic strain; anti- <i>S. aureus</i> and anti-IL-36γ; topical	IND-enabling	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	IND submission planned summer 2024
	 LUTRIS	LUT-014	B-Raf inhibitor; topical	Phase 2	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>		Phase 1 showed effect but did not reach statistical significance
	 HOTH THERAPEUTICS	HT-001	Immune cell inhibitor; topical	Phase 2	<input checked="" type="checkbox"/>			505(b)(2) pathway. No previous clinical data
Ex-US	 twiB	AC-707	Antibiotic and anti-inflammatory; topical	Phase 2	<input checked="" type="checkbox"/>			No updated Phase 2 data since trial completion in 2021
	 DAEWOONG	DWP708	Human HGF spray; topical	Phase 2 (Korea)	<input checked="" type="checkbox"/>			Korean IND cleared in 2022
	 GENOME & CO	GEN-501	Microbiome-based therapy	Preclinical	<input checked="" type="checkbox"/>			Little information available