



CORPORATE PRESENTATION | OCT 2024 | NASDAQ: SCNI

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# SAFE HARBOR STATEMENT

This communication contains forward-looking statements within the meaning of the Private Litigation Reform Act of 1995. Words such as “expect,” “believe,” “intend,” “plan,” “continue,” “may,” “will,” “anticipate,” and similar expressions are intended to identify such forward-looking statements. All statements, other than statements of historical facts, included in this communication regarding strategy, future operations, future financial position, future revenue, projected expenses, prospects, plans and objectives of the management of Scinai Immunotherapeutics Ltd. (“Scinai”) are forward-looking statements. Examples of such statements include, but are not limited to, statements regarding the therapeutic and commercial potential of nanosized antibodies (NanoAbs) and Scinai's CDMO services and capabilities; the pipeline market potential; the projected growth of sales of drugs for mild to moderate psoriasis; and the timing of NanoAb proof-of-concept studies and clinical trials. These forward-looking statements reflect management’s current views with respect to certain current and future events and are subject to various risks, uncertainties and assumptions that could cause results to differ materially from those expressed or implied by such forward-looking statements. Such risks and uncertainties include, but are not limited to, those related to: the possibility that the therapeutic and commercial potential of NanoAbs will not be met; potential changes in the pipeline market potential; a delay in the preclinical and clinical data for NanoAbs, if any; Scinai’s ability to regain compliance with Nasdaq listing requirements and maintain its listing on Nasdaq and its ability to secure additional capital on attractive terms, if at all; Scinai’s ability to acquire rights to additional product opportunities; Scinai’s ability to enter into collaborations on terms acceptable to Scinai or at all; timing of receipt of regulatory approval of Scinai’s manufacturing facility in Jerusalem, if at all or when required; the manufacturing facility will not be able to be used for a wide variety of applications and other pharmaceutical technologies; and those inherent in drug development, which involves a lengthy and expensive process with uncertain outcomes. More detailed information about such risks and uncertainties can be found in the Company’s filings with the Securities and Exchange Commission (the “SEC”), including those set forth in the section entitled “Risk Factors” in the Company’s Annual Report on Form 20F filed with the SEC on May 15, 2024. Scinai undertakes no obligation to revise or update any forward-looking statement.

# 2024: BUILDING ON 2023'S MOMENTUM

## PIPELINE DEVELOPMENT

- Licensed anti-IL-17 NanoAb
- Completed ex-vivo study: Potential psoriasis treatment
- COVID-19 NanoAb: In-vivo studies: Prophylactic & Therapeutic

- Anti-IL-17 NanoAb in-vivo psoriasis study
- Ready for first-in-human clinical trial
- Strengthen pipeline

2023

2024

## BUSINESS DEVELOPMENT

- Launched Scinai Bioservices CDMO
- Capital infusions
- New name, new brand

- More CDMO clients
- Pursue partnerships



## Our Mission

Building a healthier and happier world  
by developing, manufacturing and  
commercializing innovative  
inflammation and immunology (I&I)  
biological products primarily for the  
treatment of autoimmune and  
infectious diseases.



Shavu'ot Holiday gathering

# TWO COMPLEMENTARY BUSINESS UNITS



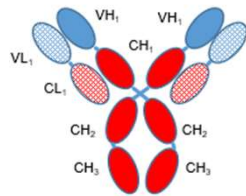
Development of inflammation and immunology (I&I) biological therapeutic products beginning with pipeline of nanosized VHH antibodies (NanoAbs) targeting diseases with large unmet medical needs



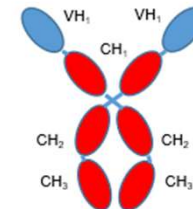
End-to-end boutique CDMO services to help bring products to market by leveraging Scinai's GMP and non-GMP drug development and manufacturing capabilities



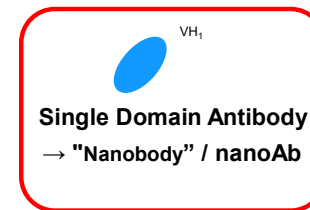
# NANOSIZED ANTIBODY PIPELINE: HUGE OPPORTUNITY



Conventional Antibody (IgG)



Heavy Chain Only Antibody



1. VHH antibody is trademarked by ABLYNX N.V., a wholly owned subsidiary of Sanofi, as Nanobody. Scinai has no affiliation with and is not endorsed by Sanofi.
2. <https://www.researchandmarkets.com/reports/5791212/monoclonal-antibody-therapeutics-market-source> (accessed 14.Aug.2023)
3. <https://www.reporting.novartis.com/2022/novartis-in-society/performance-in-2022/financial-performance.html> (Accessed 7.Jan.2024)

# MAX PLANCK, UMG, SCINAI COLLABORATION

Covering discovery and initial characterization of NanoAbs aimed at predefined list of molecular targets.

Designed to create significant clinical and commercial advantages.

## Scinai brings...

- Recombinant protein drug development experience from lab to Phase 3 clinical trial
- Manufacturing, quality, international regulatory experience
- GMP biologics manufacturing facility
- Best-in-class equipped labs
- Top-tier big pharma & biotech leadership expertise



## The Max Planck Institute & UMG<sup>1</sup> bring...

- World-class science & access to leading scientists
- NanoAb platform for the development of promising potent therapeutics
- Patents covering NanoAbs & their manufacturing



**MAX PLANCK INSTITUTE**  
FOR MULTIDISCIPLINARY SCIENCES



### **Professor Dr Dirk Görlich**

Director of Max Planck Institute for Multidisciplinary Sciences  
Winner of inaugural World Laureates Association (WLA) Prize in Life Sciences or Medicine



### **Professor Dr Matthias Dobbstein**

Fellow at Max Planck Institute for Multidisciplinary Sciences  
UMG Head of Department

1. Max Planck Institute for Multidisciplinary Sciences and the University Medical Center Göttingen (UMG)

# PLATFORM VALUE PROPOSITION

NanoAbs' unique physicochemical attributes can generate multiple crucial advantages vs human monoclonal antibodies (mAbs)



## Manufacturing

- 10-times more active pharmaceutical ingredients (API) per gram of manufactured protein vs. mAbs
- Faster and lower cost production in yeast (pichia) vs mammalian cells



## R&D

- Quicker antibody discovery and optimization due to massive libraries
- De-risked pipeline development leveraging approved mAb targets



## Product

- Hyper-thermostable = longer shelf life, easier storage & distribution
- Superior specificity & affinity to target potentially enables lower dose, fewer adverse events, lower cost
- Adaptable half life



## Patient Safety & Convenience

- Multiple, easier routes of administration
- Lower immunogenicity
- Fewer contraindications
- Potentially safer & lower dose



# DERISKED DRUG DEVELOPMENT

NanoAbs feature a favorable path to market compared to risks associated with traditional drug development

## Source of Risk

## NanoAb

### Molecular Target



Validated by existing but sub-optimal mAb therapies

### Mechanism of Action



Well understood

### Composition of Matter

TBD

Assessing safety & efficacy of alpaca-derived NanoAbs

### Commercial



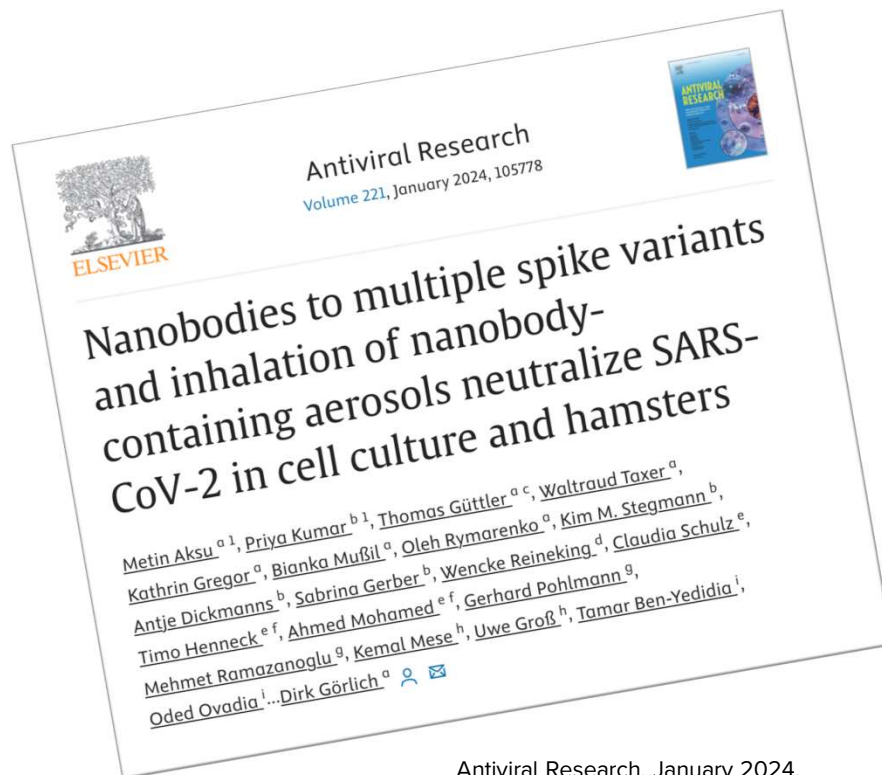
Strong demand for available mAbs and underserved populations

### Validated Therapeutic Use

First commercial VHH-antibody is blood disorder therapy Caplacizuma – by Ablynx, a company acquired by Sanofi in 2018 for \$4.8B

# SUPERIOR ROUTES OF ADMINISTRATION

**Proof-of-concept: Aerosolized NanoAbs for treatment and prevention of viral infectious diseases**



Antiviral Research. January 2024.  
<https://doi.org/10.1016/j.antiviral.2023.105778>

Paper covers several aspects of Scinai's anti-COVID-19 NanoAbs, including:

- Structure
- Mechanism of action
- Neutralization of a wide range of SARS-CoV-2 variants including Omicron
- Production in yeast
- Formulation into aerosols

Describes in vivo studies indicating that “exposing hamsters to these aerosols, before or even 24 h after infection with SARS-CoV-2, significantly reduced virus load, weight loss and pathogenicity,” concluding that these results show the significant potential of aerosolized NanoAbs for the prevention and treatment of coronavirus infections.

# PIPELINE MOLECULAR TARGETS



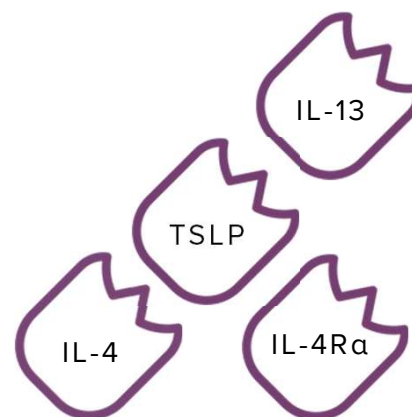
COVID-19

- Strong in vivo data for inhaled therapeutic and prophylactic in a challenge study conducted with Fraunhofer ITEM and TiHO



PSORIASIS, PSA,  
HS

- Single compound targeting IL-17A and IL-17F and IL-17AF
- Novel local use
- Larger target population than the one addressed by mAbs such as Cosentyx or Taltz and Siliq



ASTHMA,  
ATOPIC DERMATITIS

- Potential for various bi-specific combinations
- Potential for novel routes of administration (e.g. Inhalation or ID) in addition to systemic SC
- Huge potential for best in class
- Larger target population than SOC



WET AMD

- Targets well-validated
- Limited development competition
- Large commercial opportunity

# PIPELINE DEVELOPMENT: STATUS & UPCOMING MILESTONES

Anti-IL-17 psoriasis treatment in-vivo proof-of-concept in 2024, clinical trial H1 2025

Indication	Molecular Target	Drug Discovery (Max Planck)			Manufacturing Process & Analytical Method Development	In vitro / Ex vivo	In Vivo Proof-of-Concept	Toxicology	Clinical Phase 1/2	
		Alpacas Immunized	VHH Antibody Selected	Clones Generated						
Covid-19 Therapeutic	RBD	<div></div>						Ready for Partnering		
Covid-19 Prophylactic	RBD	<div></div>						Ready for Partnering		
Psoriasis, PSA, HS	IL-17A, F, AF	<div></div>						Est. H1 2025	Est. H2 2025	
Asthma, Atopic Dermatitis	IL-4Ra IL-13 IL-4 TSLP	<div></div>							Est. 2025/6 Est. 2025/6 Est. 2025/6	
Wet AMD	VEGF-A ANG-2	<div></div>							TBD TBD	

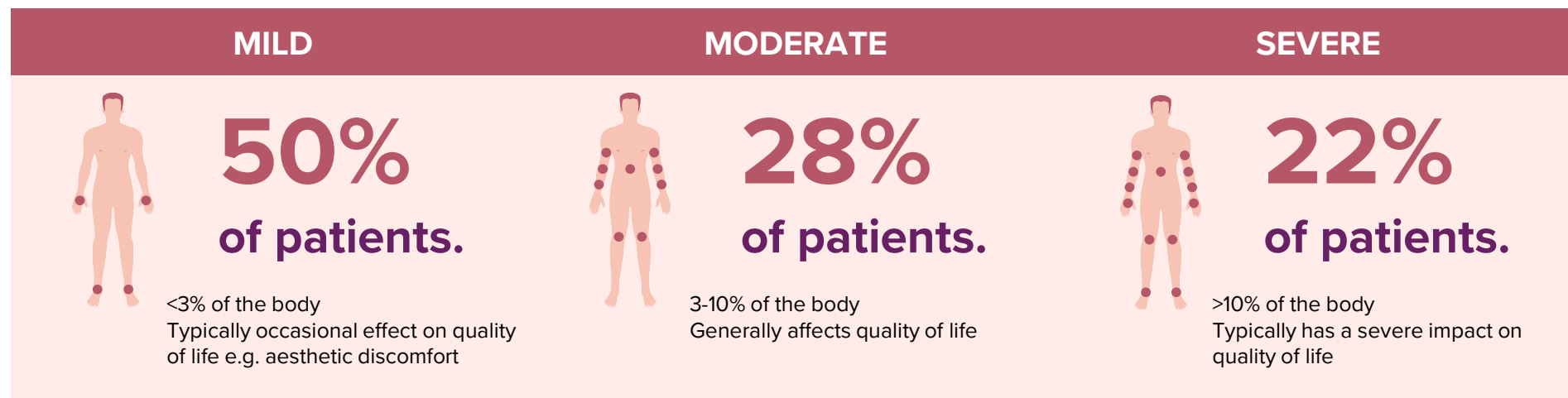
Est. – Estimated timing

# PSORIARIS: 78% UNDERSERVED POPULATION

## Mild to moderate patients underserved by current treatments

- 125 million patients, including 15.7 million in the 7 major markets (US, EU5 and Japan); 80-90% is plaque psoriasis
- Current biological therapies targeted only to moderate & severe patients, administered systemically
- Mild patients may suffer from considerable and visible lesions which may be uncomfortable, painful, and impact social and mental well-being
- Mild patients are ineligible for biological treatments; and moderate psoriatic patients are often reluctant to receive systemic biological treatments due to side effects and costs

## Psoriasis prevalence and severity



Sources: Canadian Psoriasis Network; National Psoriasis Foundation; <https://link.springer.com/article/10.1007/s13555-021-00518-8>

# CURRENT PLAQUE PSORIASIS TREATMENTS

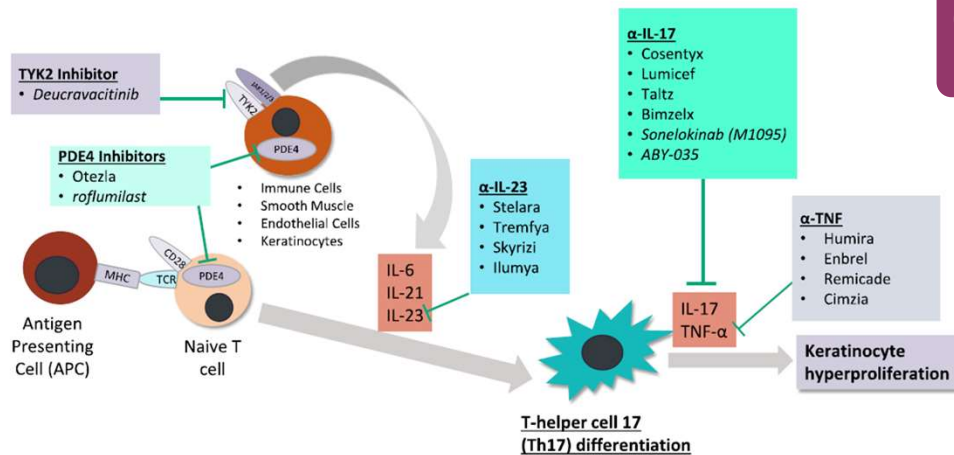
Corticosteroid creams, vitamin E+A,  
vitamin D derivatives

Phototherapy

1<sup>st</sup> line systemic immunosuppressants  
(Methotrexate and Cyclosporine) &  
Immunomodulators (Otezla)

2<sup>nd</sup> line systemic Immunomodulators  
(e.g. Sotyktu)

Injectable biologics (anti- TNF $\alpha$ , IL-17,  
IL-23)





# NANOABs ADDRESS UNMET NEED

Designed to be  
convenient, safe,  
affordable, effective  
biologic for mild and  
moderate patients

## Current treatment shortcomings

### Corticosteroids

- Side effects include:
  - Skin thinning (bruising) & Lightening of skin color
  - Development of tolerance

### Phototherapy

- Requires 20-35 sessions, 3 times a week

### 1st line systemic immunosuppressants & Immunomodulators

- E.g. Methotrexate (5.8M prescriptions in the USA in 2020) and Cyclosporin (2.2 million prescriptions) come with concerns for health risks and adverse effects. Otezla (PDE4 Inhibitor) has limited efficacy and requires daily dosing.

### 2nd line systemic Immunomodulators (e.g. Sotyktu)

- Expensive
- Limited efficacy (lower than Biologics)
- Systemic and chronic, with systemic side effects

### Injectable Biologics (mAbs)

- Limited to moderate-to-severe patients
- Very expensive
- Systemic and chronic; Increased risk of developing side effects such as psychological illness (suicidal thoughts) and inflammatory bowel disease.

# The problem: unmet need for local treatment

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- Even mild patients can suffer considerable burden of disease when they have lesions in visible or sensitive areas still cause.
  - ✓ Corticosteroids require frequent applications and generate side effects (skin atrophy) – prescription fill rate <10%
  - ✓ Phototherapy is inconvenient and cannot be used with sensitive areas – adherence to treatment <30%
  - ✓ Yet, they are not eligible for systemic therapy (biologics and JAK inhibitors - only moderate-to-severe disease)
- Some patients have psoriasis in difficult-to-treat areas such as hands, feet, scalp, genitals...
- Not all patients achieve complete clearance (PASI90 or PASI100) and some suffer from recalcitrant lesions that do not respond adequately due to comorbidities
- Systemic treatments weaken the immune system - infections
- Systemic (injectable) biologics are very expensive and indicated for moderate to severe

Credit:

**Prof. Michael P. Schön**, Department of Dermatology, Venereology and Allergology  
Lower Saxony Institute of Occupational Dermatology, University Medical Center Göttingen, Germany  
<https://hautklinik.umg.eu>

# Hard-to-treat lesions: scalp

Credit:

Prof. Michael P. Schön, Department of Dermatology, Venereology and Allergology  
Lower Saxony Institute of Occupational Dermatology, University Medical Center Göttingen, Germany  
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# Visible areas with high burden of disease: face

Credit:  
**Prof. Michael P. Schön**, Department of Dermatology, Venereology and Allergology  
Lower Saxony Institute of Occupational Dermatology, University Medical Center Göttingen, Germany  
<https://hautklinik.umg.eu>





# Hard-to-treat lesions: hands

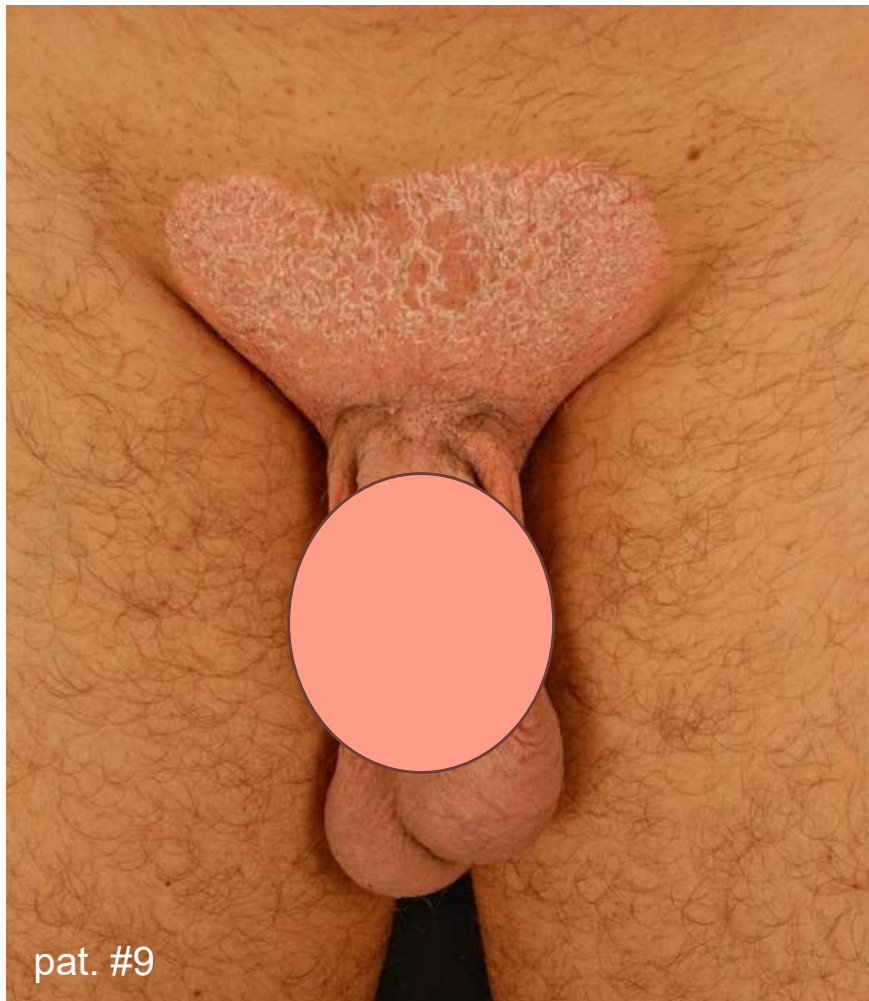
**Credit:**  
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<https://hautklinik.umg.eu>





## Sensitive areas with high burden of disease: ano-genital region

**Credit:**  
**Prof. Michael P. Schön**, Department of Dermatology, Venereology and Allergology  
Lower Saxony Institute of Occupational Dermatology, University Medical Center Göttingen,  
Germany  
<https://hautklinik.umg.eu>



# Special locations: navel and nipples

**Credit:**

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<https://hautklinik.umg.eu>



Navel with psoriasis

pat. #13

image courtesy of Prof. D. Thaci, Lübeck



Right nipple healthy



Left nipple with psoriasis



# Recalcitrant isolated lesions

Credit:

Prof. Michael P. Schön, Department of Dermatology, Venereology and Allergology  
Lower Saxony Institute of Occupational Dermatology, University Medical Center Göttingen, Germany  
<https://hautklinik.umg.eu>



# Pretreated lesions with therapy side effects: soles

**Credit:**  
**Prof. Michael P. Schön**, Department of Dermatology, Venereology and Allergology  
Lower Saxony Institute of Occupational Dermatology, University Medical Center Göttingen, Germany  
<https://hautklinik.umg.eu>



After treatment with Corticosteroids



Before treatment with Corticosteroids

# The solution: Local ID injection of Anti-IL-17A/F VHH antibody fragment

## Benefits:

- **Improves patient's convenience** by allowing local drug administration once in a couple of months, sparing the need for twice a day application of creams and ointments that makes day to day activities cumbersome or the need to attend three times a week a phototherapy center for 10 weeks long.
- **High efficacy:** Biologics are potent and specific and hence are preferred by patients and physicians. However, biologics treatments are currently approved only for moderate to severe psoriasis since they are provided systemically and come with associated risks. Scinai's nanoAb is for local administration for local action. No systemic impact
- **Differentiation** - Most other companies working with VHHs (nanobodies®) tend to mimic mAbs “playbook” by going after systemic administration while competing for higher efficacy and hence are competing for the same patient populations. Scinai's nanoAb caters to populations not covered by current biologics

# Generating incentives for the customers – the three P's

**Patients:** Mild to moderate plaque psoriasis patients.

- Currently treated with corticosteroids and are unhappy :
  - Inconvenience of use (e.g. twice a day, use of ointments/creams).
  - Development of tolerance
  - Development of side effects – thinning of the skin and changes in color of the skin.
- Cannot do phototherapy:
  - Location of lesion
  - Low compliance with phototherapy schedule
- Are pushing the physician to receive biologics
- Do not want to take daily systemic orals (Otezla or Sotyktu)
- Prefer a local, non painful treatment 2-3 times per year that saves daily treatments and at lower costs than once a month systemic biologics and without the risks of systemic immunosuppressants.

**Providers**

- Dermatologists
- Don't want to prescribe systemic biologics to mild patients (risks).

**Payers**

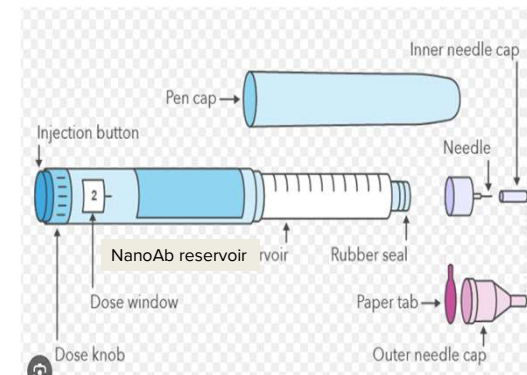
- Prefer lower costs vs. systemic biologics
- Provide their clients a superior solution vs. corticosteroids and safer than systemic biologics at a lower deductible to the patient.



# The product

An intradermal pen filled with a liquid formulation of Scinal's anti-IL-17A/F nanoAb

- Upon a patient's training by a HC provider, a pen injector with a sterile cartridge filled with 1.5 to 3ml of Scinal's formulated nanoAb drug will be dispensed by to the patient.
- A disposable and sterile ID needle of 1-3mm long will be mounted onto the pen
- The user will apply the drug in aliquots of 30 microliters each (per "click") per 7 sq/cm.
- A pen will therefore be sufficient for 50/100 aliquots (50/100 clicks on the pen) depending whether a 1.5 or a 3ml pen was used covering up to 350/700 sq cm of skin.
- As the needle is short the injection will be painless.
- A treatment will require 1 – 3 pens per patient covering up to 10% of the skin surface of an adult's body.
- Such a treatment will last 5-10 minutes and will be required every few months depending on the clinical results



# Where is the money?

	2030	CAGR (2020–2030)
<b>Drug Sales, Mild PsO (\$m)</b>	<b>\$ 1,841,500,335.5</b>	<b>12.1%</b>
<b>TNF inhibitors</b>	<b>\$ 123,915,881.2</b>	<b>0.4%</b>
Enbrel (etanercept)	\$ 21,197,962.4	-5.2%
etanercept biosimilar	\$ 17,987,481.0	31.2%
Humira (adalimumab)	\$ 31,022,633.0	-8.8%
adalimumab biosimilar	\$ 50,177,132.4	58.9%
Remicade (infliximab)	\$ 1,940,221.9	-3.4%
infliximab biosimilars	\$ 900,856.4	8.4%
Cimzia (certolizumab pegol)	\$ 307,903.1	-0.5%
certolizumab biosimilars	\$ 381,690.9	N/A
<b>IL-12/IL-23 inhibitors</b>	<b>\$ 92,770,995.3</b>	<b>0.2%</b>
Stelara (ustekinumab)	\$ 43,015,881.4	-7.2%
ustekinumab biosimilars	\$ 49,755,113.9	N/A
<b>IL-23 inhibitors</b>	<b>\$ 540,126,396.7</b>	<b>19.7%</b>
Tremfya (guselkumab)	\$ 395,863,978.0	26.8%
Ilumya (tildrakizumab)	\$ 44,223,187.6	9.9%
Skyrizi (risankizumab)	\$ 100,039,231.0	10.9%
<b>IL-17 inhibitors</b>	<b>\$ 269,947,325.1</b>	<b>17.5%</b>
Cosentyx (secukinumab)	\$ 63,619,131.3	3.8%
secukinumab biosimilars	\$ 32,516,667.7	N/A
Taltz (ixekizumab)	\$ 28,460,732.8	11.9%
ixekizumab biosimilars	\$ 6,159,350.6	N/A
Siliq (brodalumab)	\$ 1,514,817.9	8.0%
Bimzelx (bimekizumab)	\$ 63,359,429.7	N/A
sonelokimab (M1095)	\$ 42,537,922.2	N/A
izokibep/ABY-035	\$ 31,779,272.9	N/A
<b>PDE4 inhibitors</b>	<b>\$ 233,629,627.9</b>	<b>10.3%</b>
Otezla (apremilast)	\$ 141,509,024.3	4.9%
generic apremilast	\$ 86,829,302.6	N/A
roflumilast	\$ 5,291,301.0	N/A
<b>AhR Agonists</b>	<b>\$ 4,511,596.3</b>	<b>N/A</b>
tapinarof	\$ 4,511,596.3	N/A
<b>Kinase inhibitors</b>	<b>\$ 259,505,982.9</b>	<b>N/A</b>
Deucravacitinib (BMS-986165)	\$ 259,505,982.9	N/A
<b>NF-kappa B inhibitors</b>	<b>\$ 63,077,343.7</b>	<b>N/A</b>
tepilamide fumarate/PPC-06	\$ 63,077,343.7	N/A
<b>Other Systemic therapies</b>	<b>\$ 130,772,138.5</b>	<b>14.2%</b>
Methotrexate	\$ 1,537,772.3	-0.6%
Cyclosporine	\$ 34,459,452.4	0.5%
Piclidenoson	\$ 94,774,913.9	N/A
<b>Topical therapies</b>	<b>\$ 123,243,047.9</b>	<b>0.9%</b>
Wynzora (calcipotriene + betamethasone dipropionate)	\$ 1,253,390.2	N/A
generic calcipotriene + betamethasone dipropionate	\$ 15,497,482.0	0.9%
Rx Topical Corticosteroids	\$ 60,251,381.7	0.8%
Rx Vitamin D derivatives	\$ 31,849,172.6	0.8%
Rx Vitamin A/Retinoid derivatives	\$ 14,391,621.4	0.6%

- Total sales of drugs in the 7MM for mild psoriasis expected to be \$1.8B in 2030
- \$1.3B is expected to come from prescription of biologics and \$259M from TYK2 inhibitor
- This is the market where the topicals and phototherapy do not help.
- This is the unmet need, which represents approx. 300K monthly prescriptions of expensive drugs not planned for use with mild patients
- Pay attention that topicals and immunosuppressants sell altogether \$250M annually in the 7MM.

Source: GlobalData

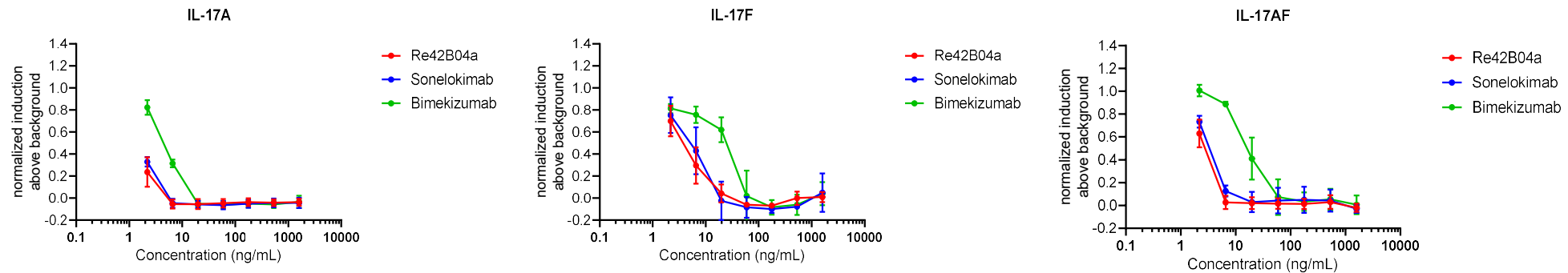
# WHY DEVELOP AN ANTI-IL-17 NANOAB?

Strong business and clinical potential for development and commercialization

Success Factor	Rationale
IL-17 is a well-established psoriasis target	IL-17 as a molecular target in psoriasis is well understood and validated by existing therapies, e.g., Cosentyx, Siliq, Taltz and Bimzelx.
Antibodies targeting IL-17A and IL-17F isoforms are more effective in treating plaque psoriasis	IL-17 F is highly expressed in the skin. UCB's Bimzelx and MoonLakes' Sonelokimab both target IL-17A and F showed superior PASI 90 scores vs. anti-IL-17A only antibodies
There is clinical evidence of IL-17 being responsive to nanobodies in treating psoriasis	MoonLake's Sonelokimab showed positive Phase II results in treating patients with <b>moderate to severe</b> psoriasis
Specific physicochemical characteristics of our drug candidate make it optimal for treatment of <b>mild to moderate</b> psoriasis (78% of patients)	Most novel oral and biological treatments tend to focus on <b>moderate to severe</b> psoriasis segment, are administered every two weeks systemically (not locally); <b>Mild to moderate</b> patients seek local treatments that are specific, efficacious and safe and that do not require chronic use.

# Scinai's anti-IL-17 Nanoab: A better neutralizer

## Single nanoAb neutralizes IL-17 A, F, and AF complex

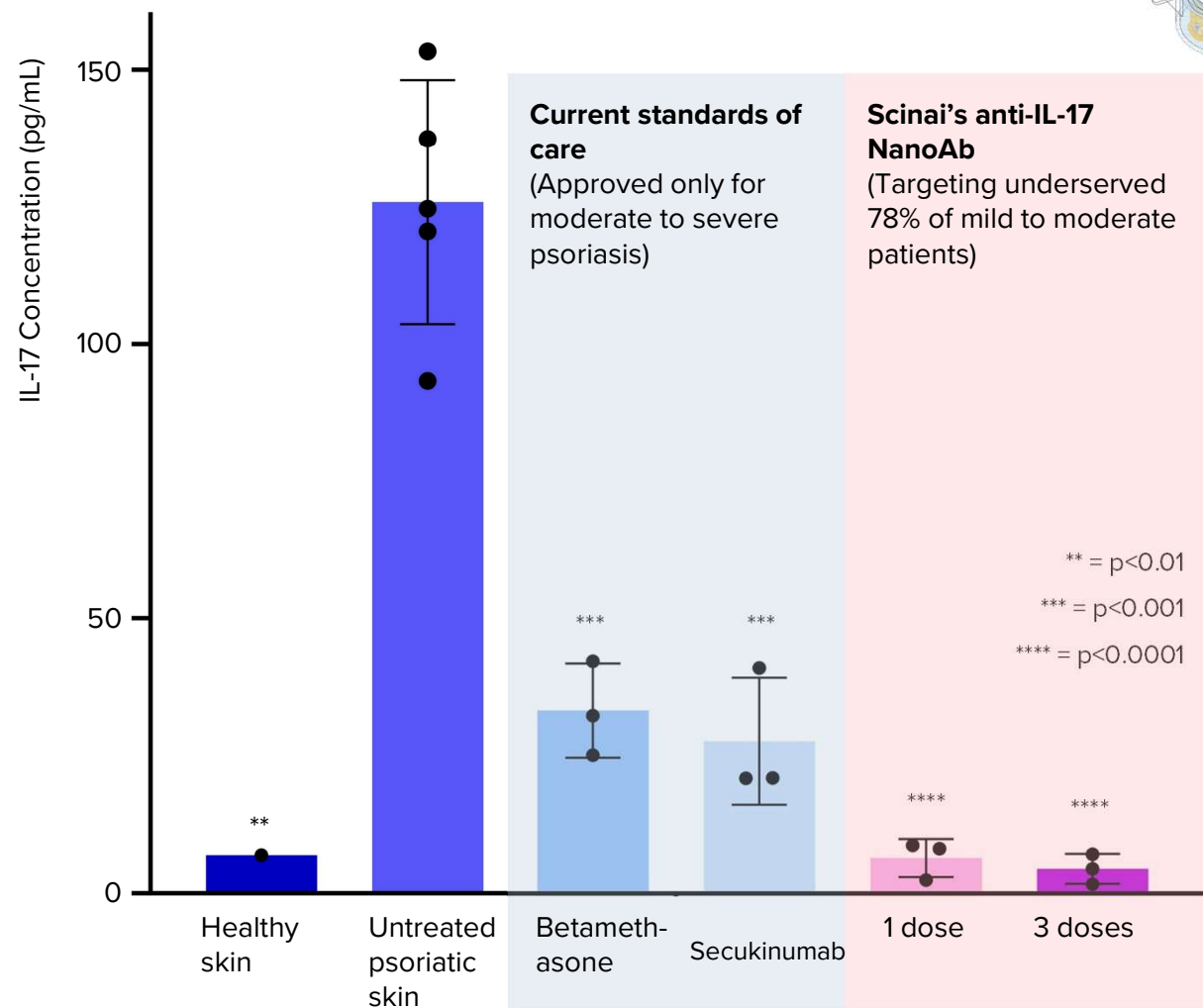


- Neutralization of IL-17 isomers by SCN-1 (Re42B04a) and other antibodies against IL-17;
- SCN-1 neutralizes IL-17A at concentrations of  $\sim 1$  nM; IL-17F at  $\sim 10$  nM and at  $\sim 1$  nM for IL-17AF;
- Neutralization was determined by the extent of eliminating the expression of the reporter gene upon blocking the induction by the IL-17 isoforms (<https://www.invivogen.com/hek-blue-il17>).

# EX-VIVO PROOF OF CONCEPT: NANOABS SHOWN TO BLOCK IL-17

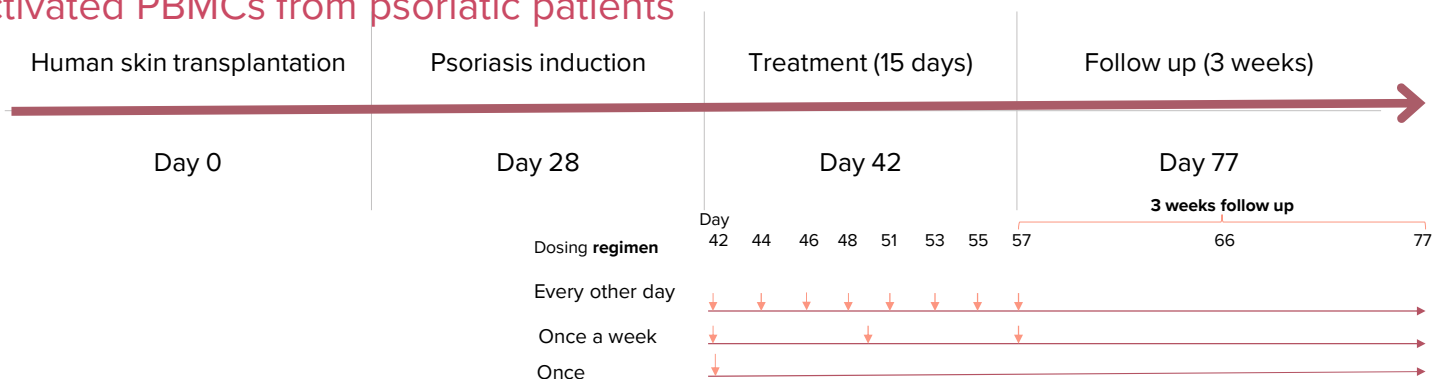
Impact of ID injected nanoAb in comparison to current leading treatments Betamethasone and Secukinumab

Designed to be local, less frequent use, safer, more convenient and more affordable



# In vivo PoC: Human xenograft skin

Animal model: Normal human skin engrafted into SCID BEIGE mouse and disease induced by injection of IL-2 activated PBMCs from psoriatic patients



## Study design

#	Role	Compound	Route	Dose	Frequency	Follow up	N
1	Negative control	Irrelevant VHH	ID	0.35 mg/injection	Once a week × 3	3 weeks	8
2	Positive control - model	Dexamethasone	Topical	2 mg/day	Twice/day for 5 weeks	NA	8
3	Positive control – comparable antibody	Secukinumab	SC	1.5mg/injection	Once a week × 3	3 weeks	8
4	Positive control – standard of care for mild to moderate	Betamethasone	Topical	180 mg/day	Twice/day for 3 weeks	3 week	8
5	Test item	SCN-1	ID	0.35 mg/injection	Every other day	3 weeks	8
6	Test item	SCN-1 (350mcg/injection)	ID	0.35 mg/injection	Once a week × 3	3 weeks	8
7	Test item	SCN-1 (350mcg/injection)	ID	0.35 mg/injection	Once	3 weeks	8

## Study endpoints

- Epidermal thickness scoring
- Macroscopic evaluation
- Analysis of psoriasis markers

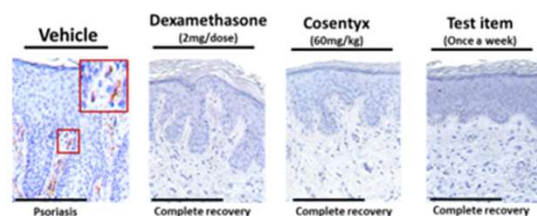


# Expression of markers in skin xenografts: IL-17 isoforms

IL-17A expression (red frame)

Observed in the negative control

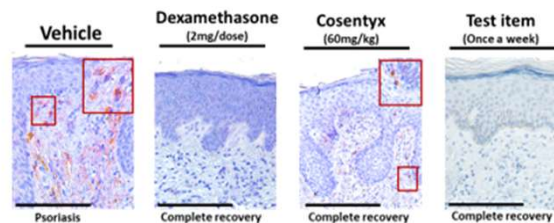
Blocked by NanoAb and the other therapies



IL-17F expression (red frame)

Observed in the negative control and in Secukinumab

Blocked by NanoAb and the steroid treatment



Negative control



Secukinumab



NanoAb (Once a week)



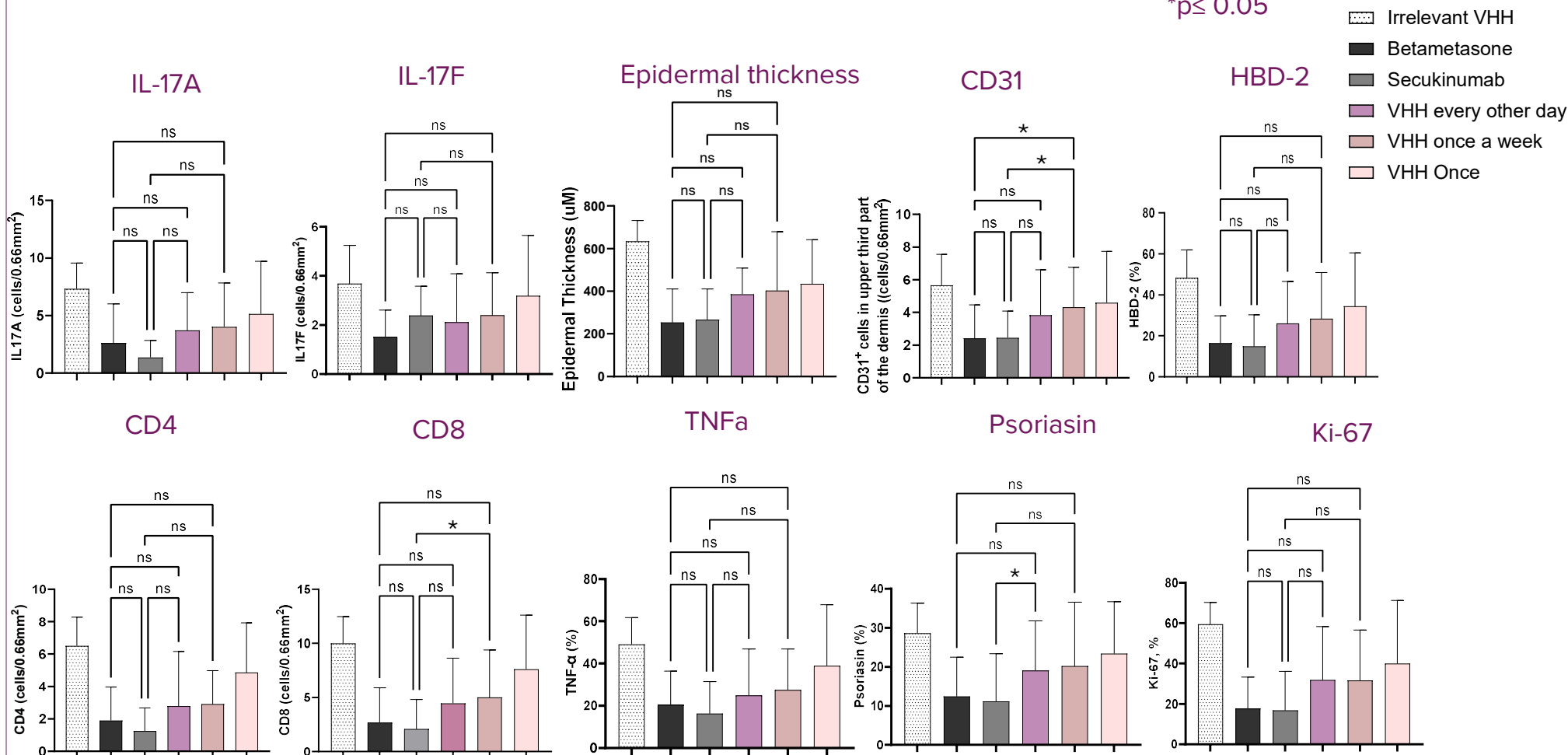
At study termination, samples from mice transplanted with skin from the same donor show scales and psoriatic appearance in the Negative control and healed lesions in the Secukinumab and NanoAb treatments.

# Parameters evaluated during the PoC – Psoriasis markers

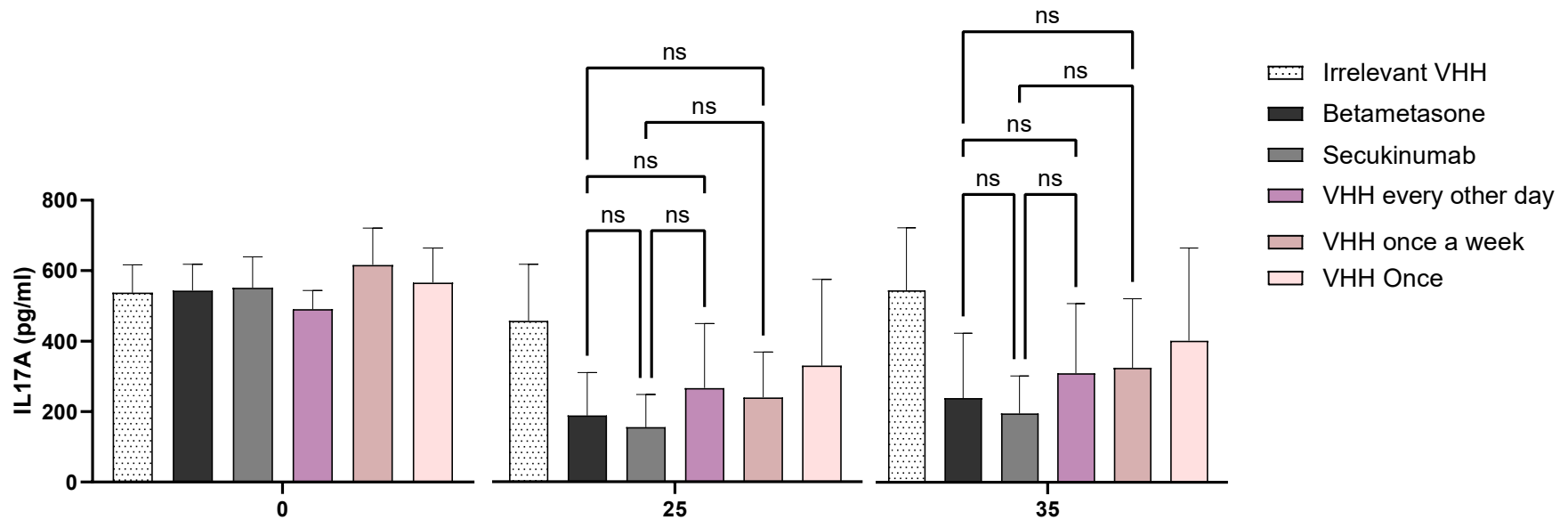
Marker	Function	Level in psoriasis
<b>Psoriasin (S100A7)</b>	Regulates cell proliferation and differentiation	Overexpressed
<b>HBD-2</b>	Antimicrobial peptide	Overexpressed
<b>IL-17A, IL-17F</b>	Pro inflammatory cytokine	Overexpressed
<b>TNF-<math>\alpha</math></b>	Pro inflammatory cytokine	Overexpressed
<b>Ki-67</b>	Marker for proliferation	Overexpressed
<b>HLA-DR</b>	Expressed by keratinocytes	associated with increased genetic susceptibility to psoriasis
<b>CD4, CD8</b>	Indicate of active inflammation	abundant due to high level of lymphocytes
<b>CD31</b>	Role in angiogenesis and vascular integrity	Increases in Psoriasis

# Psoriasis markers: mostly comparable to Secukinumab & Betamethasone

\*p ≤ 0.05

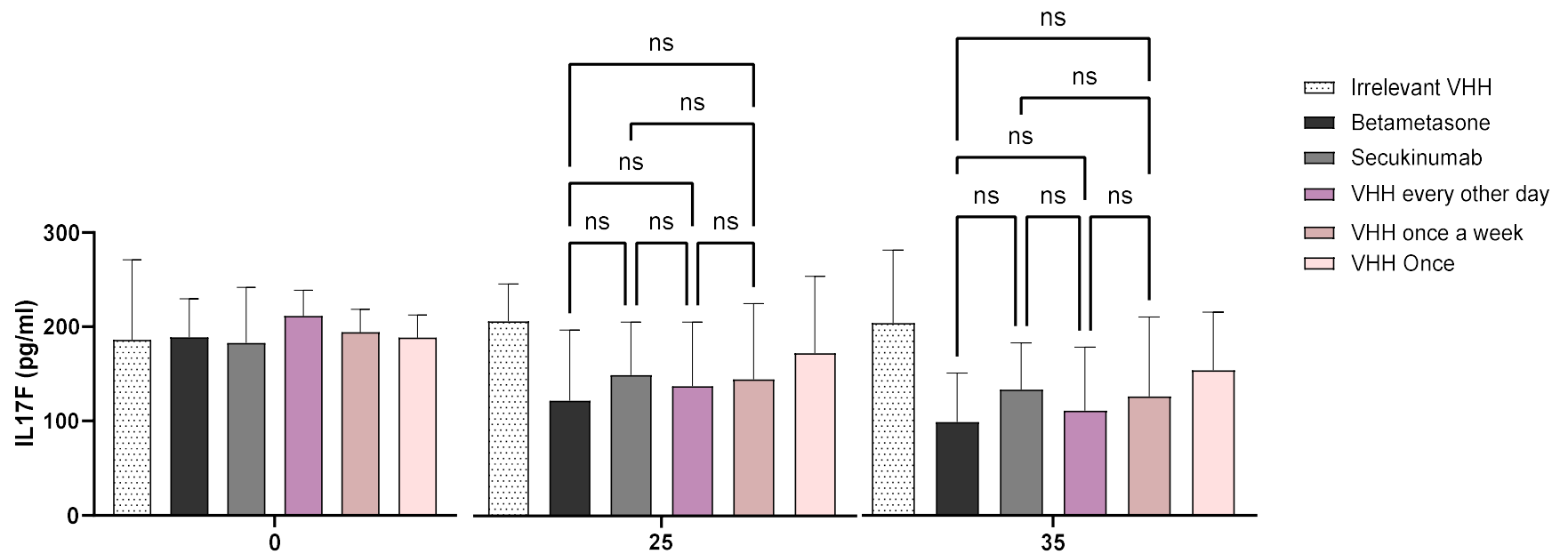


# IL-17A blood concentration after treatment initiation



- Local anti IL-17 NanoAb blocks IL-17A in the sera for up to 35 days after the 1st administration
- The blockade is comparable to Secukinumab and Betamethasone and significantly different from the negative control

# IL-17F blood concentration after treatment initiation



- Local anti IL-17 NanoAb blocks IL-17F in the sera for 35 days after the 1st administration
- The blockade is comparable to Secukinumab and Betamethasone and significantly different from the negative control

## Take aways from in vivo Poc

1. Mode of action verified: **SCN-1 NanoAb blocks IL-17A, F and disrupts the whole psoriatic cascade**
2. Local administration of the NanoAb into the lesion leads to **comparable effect vs. comparator drugs**
- 3. The therapeutic effect of the nanoAb lasts far beyond its t1/2**
4. Blood concentrations of IL-17 correlate with the overall therapeutic effect
5. No observed adverse effects

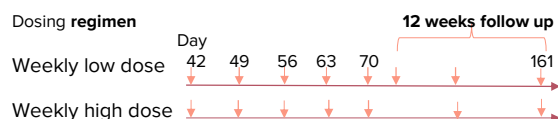
## Next steps

1. Test an increased dose together with 5 induction injections (similar to mABs) to prolong the therapeutic effect
2. Asses the durability of the therapeutic effect for up to 3 months post treatment



# Next In vivo PoC: Human xenograft skin – Optimization

Animal model: Normal human skin engrafted into SCID Beige mouse and disease induced by injection of IL-2 activated PBMCs from psoriatic patients



Study design (additional treatment will be considered according to the blood IL-17 levels)

#	Role	Compound	Route	Frequency	Bleeding (IL-17)	Termination	N
1	Negative control	Irrelevant VHH (350mcg/injection)	ID	Once a week × 5	2, 4, 6, 8, 10, weeks	12 weeks	8-10
2	Positive control - model	Dexamethasone	Topical	Twice/day for 9 weeks	NA	12 weeks	8-10
3	Positive control – comparable antibody	Cosentyx	SC	Once a week × 5	2, 4, 6, 8, 10, weeks	12 weeks	8-10
4	Positive control – standard of care for mild to moderate	Betamethasone	Topical	Twice/day for 5 weeks	2, 4, 6, 8, 10, weeks	12 weeks	8-10
5	Test item	SCN-1 (350mcg/injection)	ID	Once a week × 5	2, 4, 6, 8, 10, weeks	12 weeks	8-10
6	Test item	SCN-1 (3500 mcg/injection)	ID	Once a week × 5	2, 4, 6, 8, 10, weeks	12 weeks	8-10
							48-60

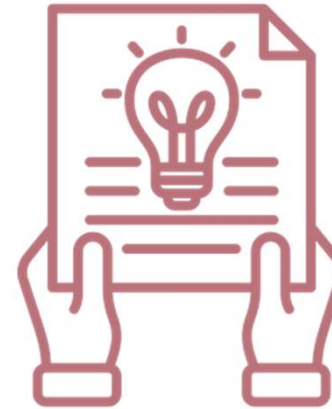
## Study endpoints

- Epidermal thickness scoring
- Macroscopic evaluation
- Immunohistochemical and blood levels analysis of psoriasis markers & IL-17A,F

## IL-17 nanoAb program summary

- There is a need for a better treatment for patients with mild to moderate Psoriasis and for specific lesions that are hard to treat with current therapies.
- Biological drugs are the safest and most efficient, yet – they are administered systemically and are expensive.
- Blocking IL-17A and IL-17F isoforms is an effective mechanism to control Psoriasis
- Scinai's NanoAbs, administered locally ID already showed superior neutralization of IL-17 in cell culture, and ex-vivo in human Psoriatic skin.
- In Scinai's in vivo study, the NanoAb was comparable to Secukinumab anti IL-17A mAb and Betamethasone in reducing multiple inflammatory parameter
- Next: Optimize schedule of administration to extend the duration of the therapeutic effect

# IP STATUS ANTI IL-17 NANOAB



## **Status**

- Priority patent application: Filed Dec. 28, 2022
- International patent application (PCT): Filed December 27, 2023

## **Covers**

- The patent application encompasses novel VHH antibodies directed against IL-17 isomers and their use for therapeutic and diagnostic applications. The VHH antibodies, characterized by specific sequences, can block the IL-17A and -F that are on the critical path for Psoriasis and other diseases.

## **Exclusive license**

- Scinai has exclusive license from the Max Planck Society for worldwide development and commercialization.

# BOUTIQUE CDMO SERVICES

De-risking Scinai's internal R&D investments by leveraging internal capabilities



**ASEPTIC GMP  
MANUFACTURING  
SUITES**



**STATE-OF-THE-ART  
R&D AND QC  
LABORATORIES**



**PHARMA CMC  
EXPERIENCE**



# GMP MANUFACTURING AND R&D LABS

Industry standard  
aseptic facility:  
Labs, cleanroom,  
warehouses, offices

- Analytical methods development combined with best-in-class **QC capabilities** and equipment
- Labs for **manufacturing process development** and scale-up allow for the implementation of quality by design and design of experiment principles
- **cGMP suites** for upstream fermentation, downstream purification, media and buffer preparations, formulation and aseptic automated filling of PFS & vials
- Designed to meet **FDA and EMA** regulatory standards
- Single-use equipment enables:
  - Adaptable manufacturing processes for a pipeline of different products
  - Quicker lead times
  - Faster time-to-market for new products

Scinai's 1850m<sup>2</sup> (20,000 sq.ft)  
cGMP Biologics Manufacturing Facility | Jerusalem





# CDMO STRATEGIC GUIDING PRINCIPLES

## Scinai's CDMO value proposition:

*Experienced and professional team available to execute drug development projects at high-speed while adhering to high (EU) quality standards using new and modern equipment located in a well-maintained site, offered at competitive pricing attractive to young biotech start-ups*

- Focus on serving Israel, Europe and USA
- Target services: Early-stage biopharma drug development projects from preclinical studies to clinical phase 2
- Target customers: Early-stage biotech companies at pre-clinical stage

# DEEP PHARMA EXPERIENCE & CAPABILITIES

## 30 STAFF MEMBERS

- 5 PhDs
- Manufacturing, engineering, technical R&D, upstream & downstream process development, QC, QA, clinical and non-clinical, procurement
- Outsourced finance, legal, regulatory



### AMIR REICHMAN – CEO

Senior global pharma leadership positions: Pharmaceutical engineering & supply chain at GSK Vaccines, Belgium; Large projects building vaccine manufacturing sites in Belgium, Italy, Germany, Hungary & US; NeuroDerm (R&D); Novartis Vaccines (Global Supply Chain).



### DR. TAMAR BEN-YEDIDIA – CSO

Co-invented and guided vaccine candidate through 8 clinical trials including pivotal Phase 3. PhD from Department of Immunology, Weizmann Institute of Science.



### ELAD MARK – COO

Led scale-up, tech transfer, manufacturing of recombinant proteins in China, mAbs for Novartis Singapore. Principal bioprocess engineer; Novartis (Technical Project Manager – Process).



### DR. DALIT WEINSTEIN-FISCHER – VP TECHNICAL R&D

Leadership roles at Merck kGaA Israel. Directed Biological Processes at NanoSpun Technologies Ltd. and CTO at VAYU Sense AG, specializing in improving bio-based fermentation processes with an AI-based controller. Led the Natural Biotechnology Systems Department at Sigma Aldrich. PhD Molecular Genetics and Microbiology.

# BOARD BRINGS SIGNIFICANT EXPERTISE

## NORTH AMERICA

### **Mark Germain, Chairman**

Aentib Group (Managing Director). Founder, director, chairman, and/or investor in over 20 biotech companies including Alexion, Incyte, Neurocrine, Ariad, ChromaDex.

### **Samuel Moed, Director**

Bristol Myers Squibb (NYSE: BMY) (Senior Vice President, Corporate Strategy)

### **Adi Raviv, External Director**

Experienced in Wall Street investment banking; Capacity Funding LLC (Principal)

### **Jay Green, External Director**

Glaxo SmithKline (NYSE: GSK) Global Vaccines (Senior Vice President Finance and CFO), Gavi (Advisor for COVAX)

## ISRAEL

### **Amir Reichman, CEO**

NeuroDerm Ltd (Senior Scientist), Novartis Vaccines USA (R&D and Global Supply chain), GSK Vaccines Belgium (Global Supply Chain and Global Engineering)

### **Morris C. Laster, Director**

BioLineRx (CEO, Director), OurCrowd (Partner), Clil Medical (CEO), Vital Spark (CEO), Kitov Pharmaceuticals (Co-founder, Director)

### **Yael Margolin, PhD, External Director**

Gamida Cell Ltd. (Nasdaq: GMDA) (President, CEO, Director), Denali Ventures LLC (VP)

### **Avner Rotman, PhD, Director**

Biodar (CEO), Rodar (Founder)

# SELECT FINANCIALS & CAP TABLE

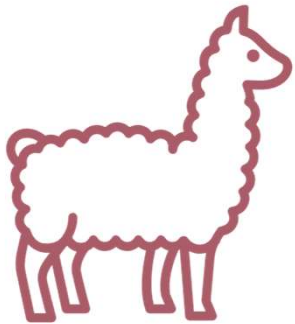
## Nasdaq: SCNI

Ordinary ADS Outstanding	838,578
1000 Preferred shares* (if converted to ADS)	364,000
\$50 warrants (Expire 16 Dec 2025)	14,000
\$6.5 warrants (Expiry 2027)	292,000
\$8.1 warrants (Expiry 2027)	8,760
\$14.5 warrants (Expiry 2028)	6,879
\$6.5 warrants (Expiry 2029)	229,310
\$8.1 warrants (Expiry 2029)	6,879
ESOP Options + RSUs	104,956
Shares + warrants + options	1,865,362

- \$3M cash as of June 30, 2024
- 1,000 preferred shares, which are expected to be issued shortly following closing of the debt-to-equity agreement with the EIB will be convertible in the aggregate into 364,000 ADSs.

# SIGNIFICANT POTENTIAL FOR VALUE CREATION

- > Pipeline of NanoAb-based drugs
- > Promising preclinical results
- > Preparing for first-in-human clinical trial of anti-IL-17 NanoAb
- > Collaboration with Max Planck Society and UMG, Germany
- > Targeting diseases with large underserved needs and attractive commercial opportunities
- > CDMO business unit buffers R&D risk





NASDAQ: SCNI

[www.scinai.com](http://www.scinai.com)

Oct 2024



# SCINAI

IMMUNOTHERAPEUTICS

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