



**Corporate Presentation**

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April 2024

# Edesa Highlights

## Advancing First-in-Class Therapeutics for Immuno-Inflammatory Diseases

### First-in-Class Targets

Toll-like Receptor 4 (TLR4)

C-X-C motif chemokine ligand 10 (CXCL10)

Secretory phospholipase A2 (sPLA2)

### Clinical Stage Pipeline and Data

**EB05:** Ph2 data in critically ill ARDS suggest potential to be standard of care

**EB06:** Phase 2 CTA in vitiligo approved, and IND being prepared

**EB01:** Phase 2b data in chronic ACD with potential to be first labelled treatment

### Demonstrated Track Record



Successfully executing clinical programs

Entrepreneurial team with strong record of partnering and exits



# First-in-Class Development Pipeline

## Advancing First-in-Class Therapeutics for Immuno-Inflammatory Conditions

Franchise	Asset	Program	Indication	Pre-Clinical	Phase 1	Phase 2	Phase 3	Status	Comments
 Respiratory	<b>Anti-TLR4</b> (mAb)	<b>EB05</b> Paridiprubart	ARDS - Covid-19	Progress bar (dark green)			Progress bar (light green)	Enrolling	Ph3 funding from the Canadian Govt; Fast Track by the FDA
		<b>EB05</b> Paridiprubart	ARDS - General	Progress bar (dark green)		Progress bar (light green)		To be initiated	Planning in progress
		<b>EB07</b> Paridiprubart	Pulmonary Fibrosis	Progress bar (dark green)		Progress bar (light green)		IND in progress	Ph2 study prep in progress
 Dermatology	<b>sPLA2 Inhibitor</b> (Small Molecule)	<b>EB01</b> Daniluromer	Allergic Contact Dermatitis (ACD)	Progress bar (dark blue)			Progress bar (light blue)	Ph3-ready	Final results released; Ph3 partnering discussions in progress
	<b>Anti-CXCL10</b> (mAb)	<b>EB06</b>	Vitiligo	Progress bar (dark blue)		Progress bar (light blue)		CTA granted; IND in progress	Ph2 PoC and drug manufacturing plans in progress

# Large Addressable Market Opportunities

Across Chronic and Acute, High-Cost Critical Care

Few FDA approved therapies and significant share of voice

Attractive health economics proposition

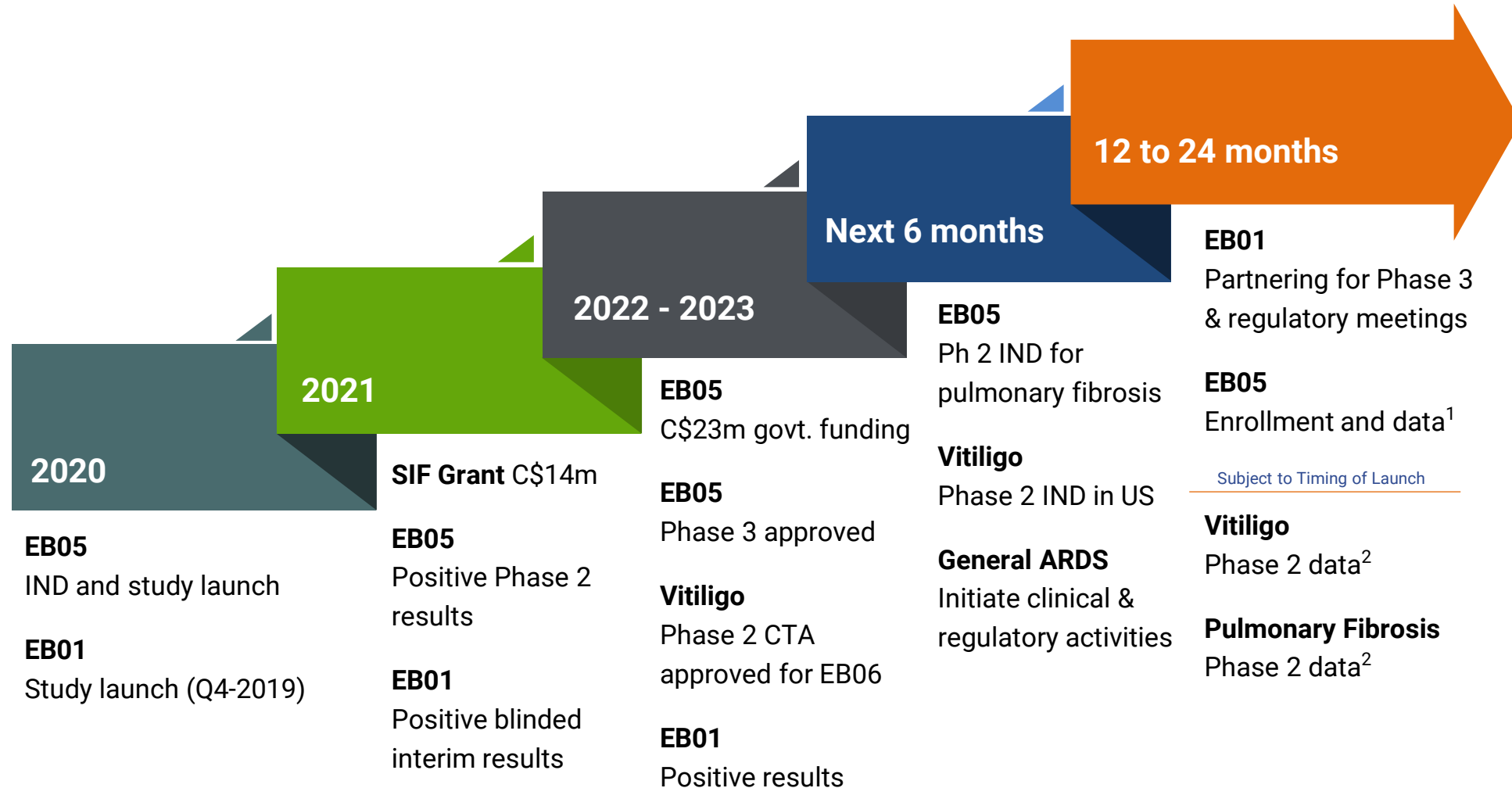
Accessible with focused commercial organization (North America)

Synergies with pipelines/interests of potential strategic partners

Total Addressable Markets\*



# Milestone-Rich Clinical Calendar





# EB05

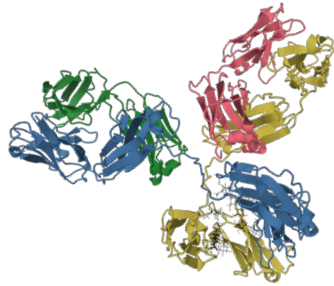
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Paridiprubart for ARDS



# Paridiprubart – Anti-Toll-like Receptor 4 (TLR4) Antibody

First-in-Class mAb that Specifically Blocks TLR4 Signalling



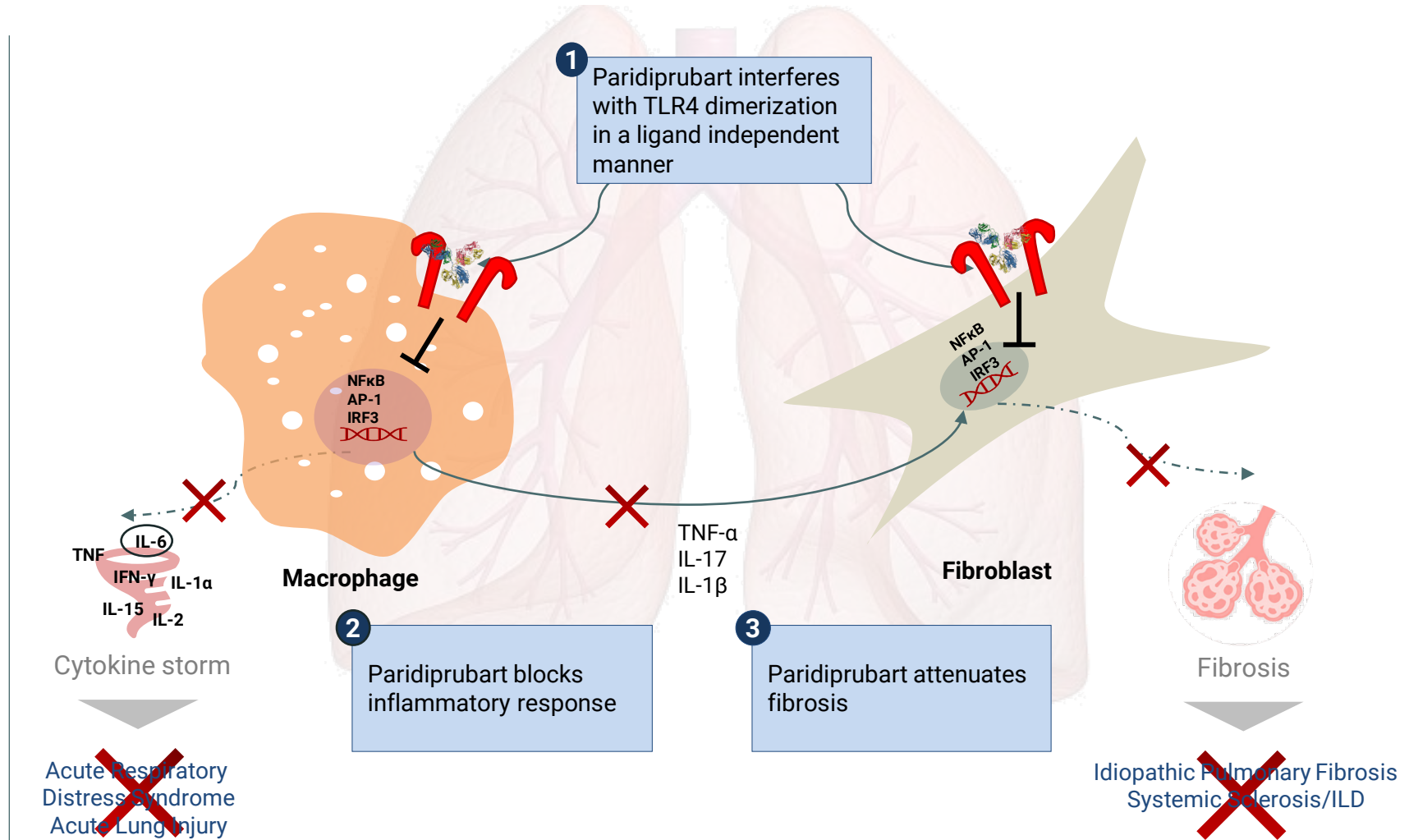
Drug Profile

A humanized IgG1k monoclonal antibody

Binds to TLR4 with high affinity

Extensive preclinical and clinical development: 600+ subjects

Multiple manuf. runs by a leading CDMO





# ARDS Treatment Paradigm

Current Options Available Rely Primarily on Supportive Care and a Small Number of Drugs

## DIAGNOSIS

The Berlin definition is the gold standard

Based on chest imaging and oxygenation levels

Oxygenation is used to classify patients as mild, moderate or severe

## TREATMENT

### Supportive

High-flow oxygen

Invasive mechanical ventilation

Extracorporeal membrane oxygenation

### Pharmacologic\*

Remdesivir

Corticosteroids

Tocilizumab

Baricitinib

Anakinra

Vilobelimab

40%

Mortality Rate

**The existing treatment paradigm is ineffective in addressing the burden of ARDS**

# A Significant Burden and Market Opportunity

## Total Addressable Market

**600,000**

Estimated ARDS-Related  
ICU Admissions/Year



**\$5.2B**

ARDS across the 7 major markets  
(US, UK, Germany, France, Spain, Italy, Japan) and Canada.<sup>4</sup>

Does not include incremental revenue due to Covid-19 cases and  
additional regions (Asia/Pacific, LATAM, Oceania, Eastern Europe, Africa)

## Disease Burden

**7 to 21 days**

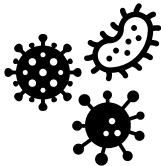
of ICU stay for surviving  
ARDS patients<sup>1</sup>

**\$100K+**

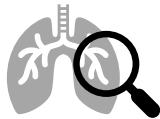
average cost per patient  
in the US<sup>2</sup>

ARDS was underdiagnosed prior to COVID-19 with 2/3  
cases with missed or delayed diagnosis<sup>3</sup>

## Growth Drivers



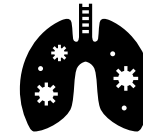
Endemic Covid-19 +  
other pathogens



Increasing awareness  
and better diagnosis



Ageing  
population



Increasing incidence of co-  
morbidities/risk factors<sup>3</sup>

# EB05 – Phase 2 Clinical Efficacy

Signal-Finding Component; Wide Population and Variety of Endpoints

## Phase 2 population

315 Hospitalized Covid-19 patients

WHO Severity scale from level 4 to level 7

## Primary endpoints

Proportion of patients alive and free of supplemental oxygen at 28 days of follow-up

## Key secondary endpoints

28-day mortality

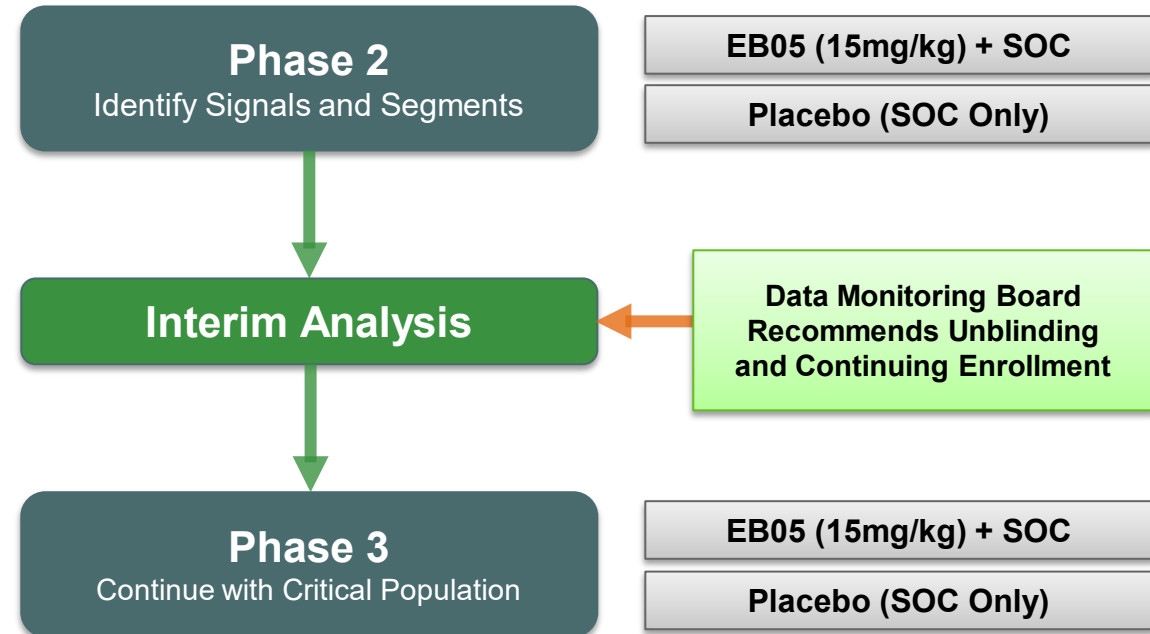
Ventilator free days

Improvement in WHO scale

Safety

**44 sites in US, Canada and Colombia**

## Efficacy of EB05 in Subjects Hospitalized with Covid-19 Infection



SOC = Standard of care



The Phase 2 trial was supported by the Government of Canada's Strategic Innovation Fund

# Phase 2 Clinical Efficacy Demonstrated

## Statistically Significant Mortality Trend in Critical Patients

### Phase 2 – Preemptively unblinded by independent data safety monitoring board (DSMB)

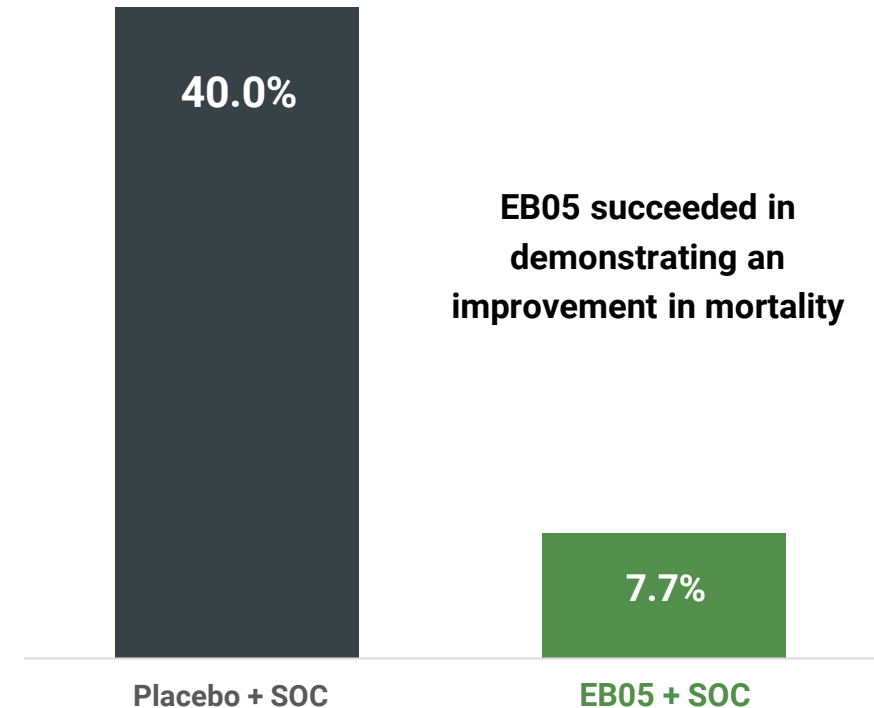
- Strong efficacy signal for 28-day mortality
- Favorable safety analysis of ~360 subjects

### Critically ill patient population\*

- 28-day death rate of 7.7% (1/13) in the EB05 arm vs. 40.0% (8/20) in the placebo arm
- 84% reduction in the risk of dying (HR: 6.124 placebo vs. EB05; 95% CI: 0.765-49.062; p=0.088).
- All patients received Standard of Care (SOC): ~85% received dexamethasone (or other steroids); >40% received both tocilizumab and a steroid; well balanced

### Profound Efficacy Signal for Mortality Reduction

(28-Day Mortality Rate; n=33, p=0.04)



# U.S./Canada Phase 3 Clinical Study

## ARDS Patients Hospitalized with Covid-19 Infection

<b>Status</b>	Recruiting
<b>Primary Endpoint</b>	28-Day Mortality
<b>Key Secondary Endpoints</b>	Ventilation Free Days 60-Day Mortality
<b>Target Population</b>	Adult subjects on invasive mechanical ventilation, both with and without additional organ support (such as ECMO)
<b>Enrollment Target</b>	~600 evaluable subjects

IMV = invasive mechanical ventilation (IMV); ECMO = Extracorporeal membrane oxygenation .

**Canada** 

**The Ongoing Phase 3 Trial is Supported by the  
Government of Canada's Strategic Innovation Fund**



# EB07

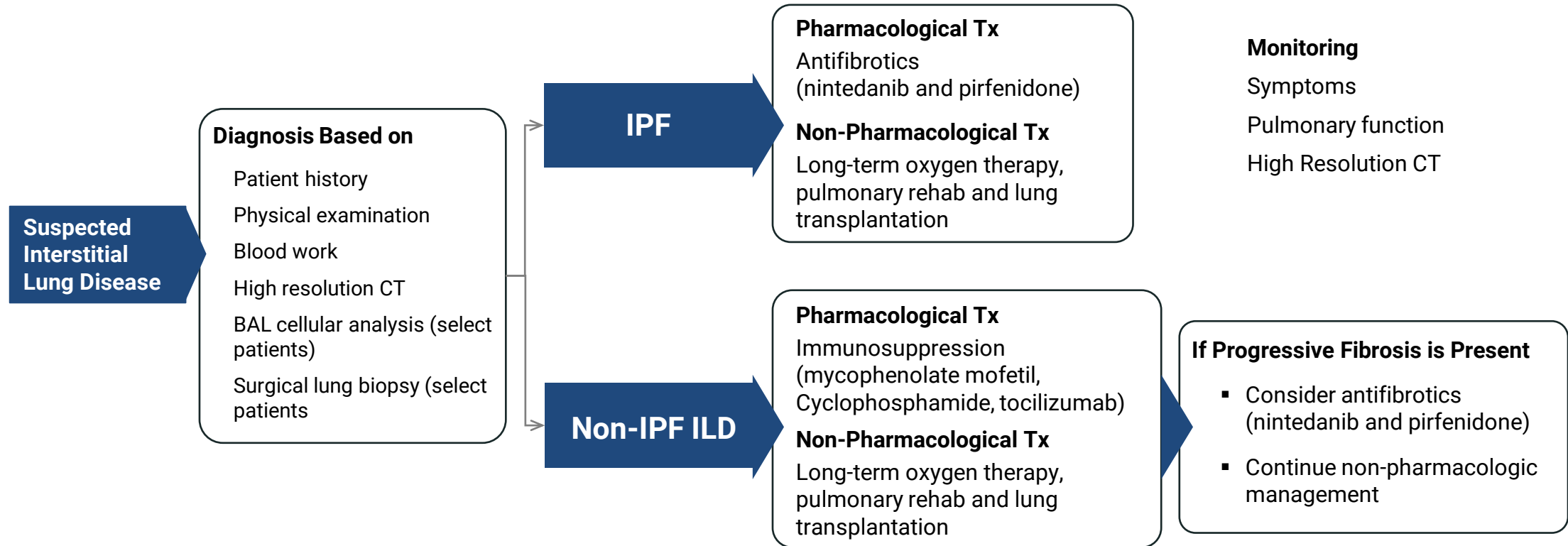
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Paridiprubart for  
Pulmonary Fibrosis



# ILD and IPF – Treatment Paradigm

Current Management Relies on Treatments that Slow Progression But Do Not Resolve/Reverse Fibrosis



**UNMET  
NEED**

**Immunosuppressants tested to date have not showed benefit in progressive fibrosis**

Antifibrotic agents Nintedanib and pirfenidone slow progression of disease but **a significant level of morbidity and mortality remains**

# IPF Burden and Market Size

A Significant Healthcare Burden and a Growing Market Opportunity

7.6

IPF prevalence per 100,000 (USA & EU)

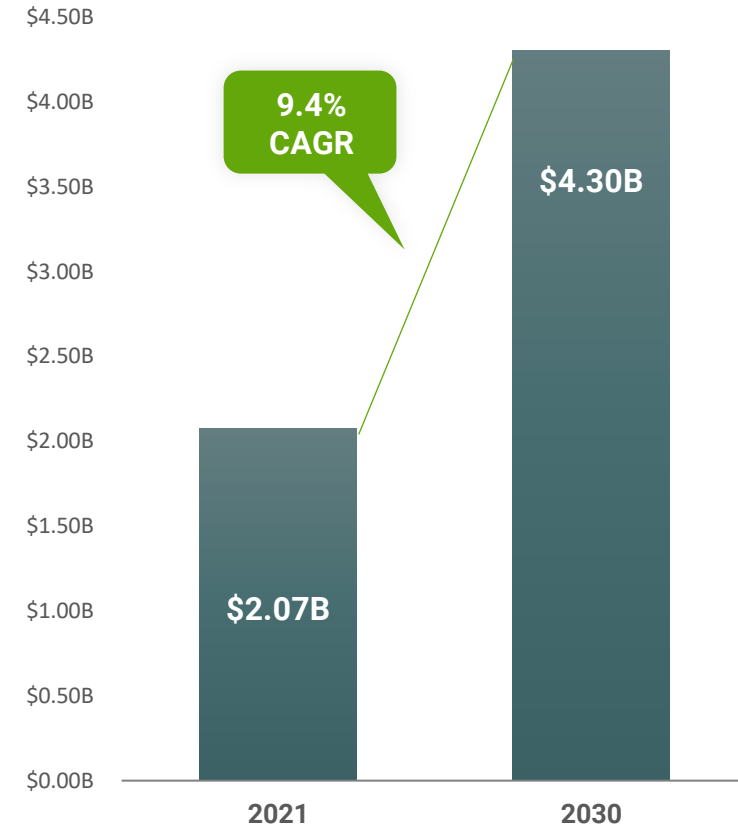
\$2B

Annual IPF-attributable medical cost to the US Health system (excl. medication costs)

\$20K

Annual medical costs per patient (USA)

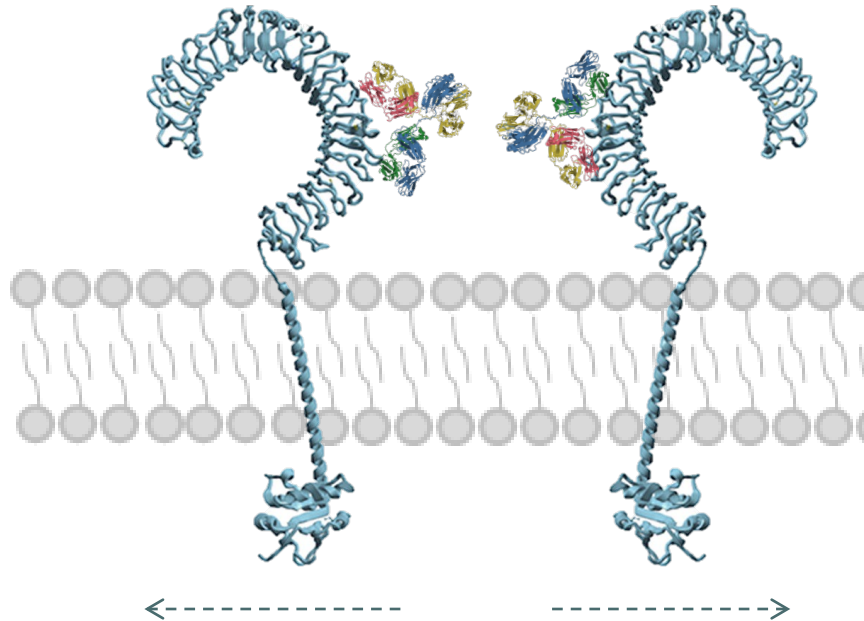
Global IPF Market



Sources: Research and Markets

# TLR4's Therapeutic Potential in Fibrotic Diseases

## Summary of Preclinical Evidence



- 1 | **TLR4 knock-out animal models display attenuated fibrosis**
- 2 | **TLR4 antagonists lead to reduced fibrosis in animal models**
- 3 | **TLR4 antagonists can reverse fibrosis in animal models**
- 4 | **TLR4 agonists are predictors of disease progression and severity**

# Leveraging Existing Work from the ARDS Program (EB05)

Same Antibody as EB05 with a Significant Amount of Previous Preclinical, Clinical and Manufacturing Work



## Biological Activity in Humans Established

Inhibition of cytokines and physiological response



## Favorable Safety Profile

236 patients and healthy volunteers administered with a single dose (20mg/kg)

56 patients with multi-dose (5mg/kg) every 4 weeks for 16 weeks



## Efficacy and Safety Experience

10+ years of preclinical and clinical work



## Manufacturing by Leading Global CDMO

Multiple Successful GMP Runs

High concentration suitable for subcutaneous already formulated (150mg/ml)



# Proposed U.S. Phase 2 Clinical Study

## Patients with Idiopathic Pulmonary Fibrosis

<b>Status</b>	IND being prepared – 15mg/kg/4 weeks
<b>Anticipated Duration</b>	24 Months - Enrollment & Data
<b>Primary Endpoint</b>	Absolute Change From Baseline in Forced Vital Capacity (FVC) at 52 weeks
<b>Key Secondary Endpoints</b>	Absolute Change From Baseline in 6-Minute Walk Test (6MWT) Distance Absolute Change From Baseline in Percentage of Predicted FVC
<b>Target Population</b>	FVC $\geq$ 45% predicted during screening Documented diagnosis of IPF
<b>Enrollment Target</b>	~150 evaluable subjects

# EB06 - Vitiligo

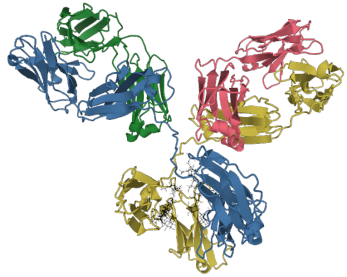
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First-in-Class Anti-CXCL10 mAb



# EB06 – Targeting the Chemokine CXCL10

Monoclonal Antibody that Directly Binds CXCL10 with High Affinity and Blocks it from Binding to CXCR3



## Drug Profile

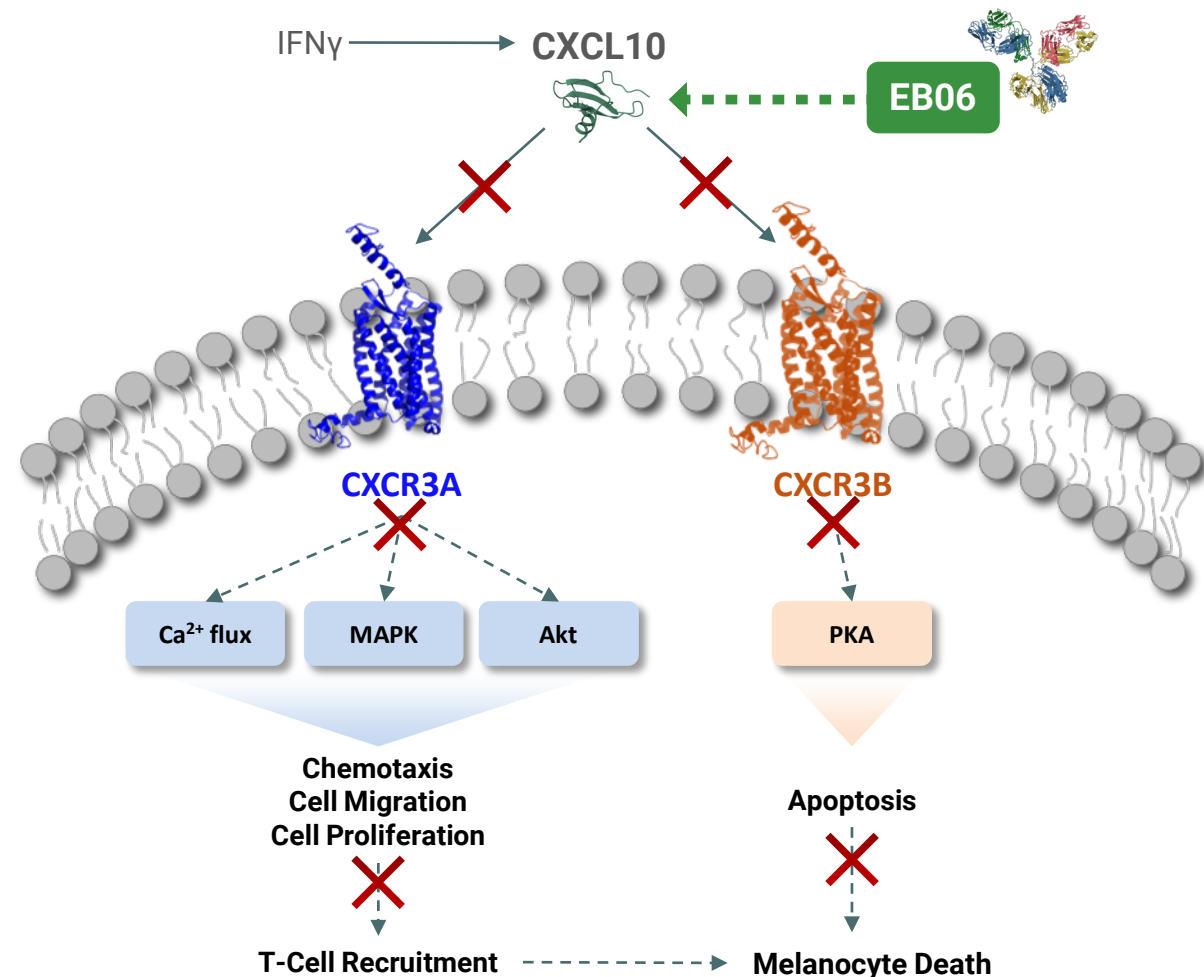
A humanized IgG1k monoclonal antibody

Binds specifically to CXCL10 with high affinity

65 patients dosed

Sequesters and renders CXCL10 inactive

Multiple manuf. runs by a leading CDMO



# Vitiligo Treatment Paradigm

Limited Options with Topical Ruxolitinib as the Only Approved Product

## TREATMENT

### Topicals

Corticosteroids

Calcineurin inhibitors

Ruxolitinib

### Phototherapy

Systemic Steroids

### Surgery

Skin grafting

Hair follicle transplant

## Significant Unmet Need

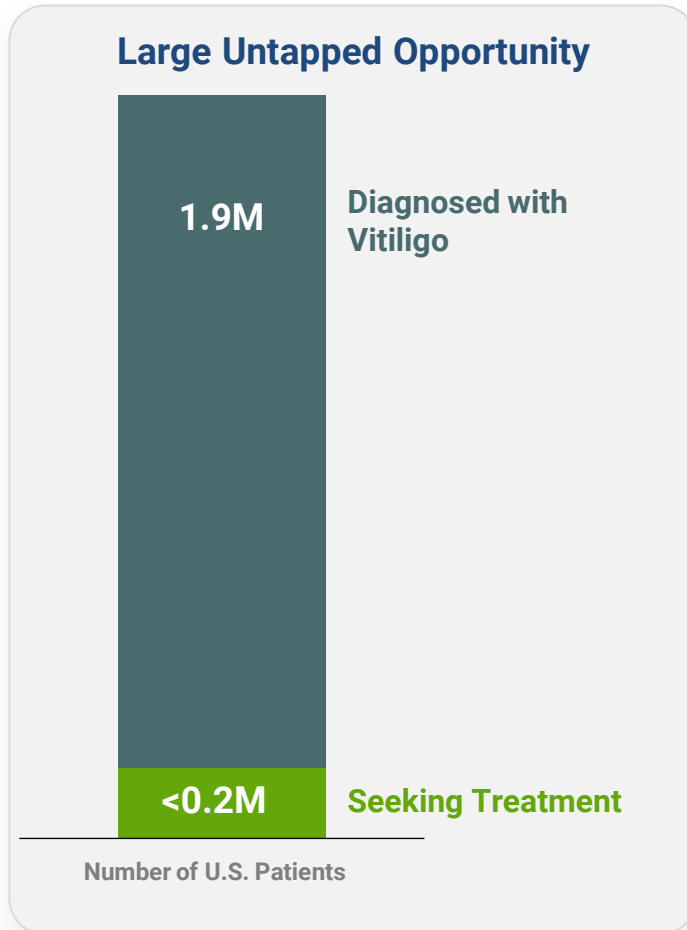
Large unaddressed market due to lack of approved and effective options

Only one approved drug with safety concerns (black box warnings)

Need for safe and effective systemic options, especially for high body surface area

# A Significant Unaddressed Market

Latent Market Comprised of Patients Waiting for Better Treatment Options

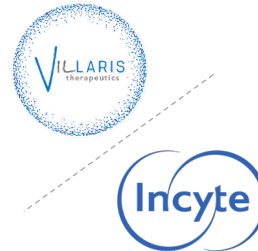


Large population but low proportion of patients seeking treatment due to **lack of effective and safe treatments**

**New therapies likely to drive market growth**

Opzelura is the only approved product and is poised to realize net sales of >\$100M within 3 quarters of launch despite safety concerns

Need for new options underscored by recent M&A activity



**Villaris was acquired by Incyte in late 2022 for up to \$1.36B, including \$70M upfront**

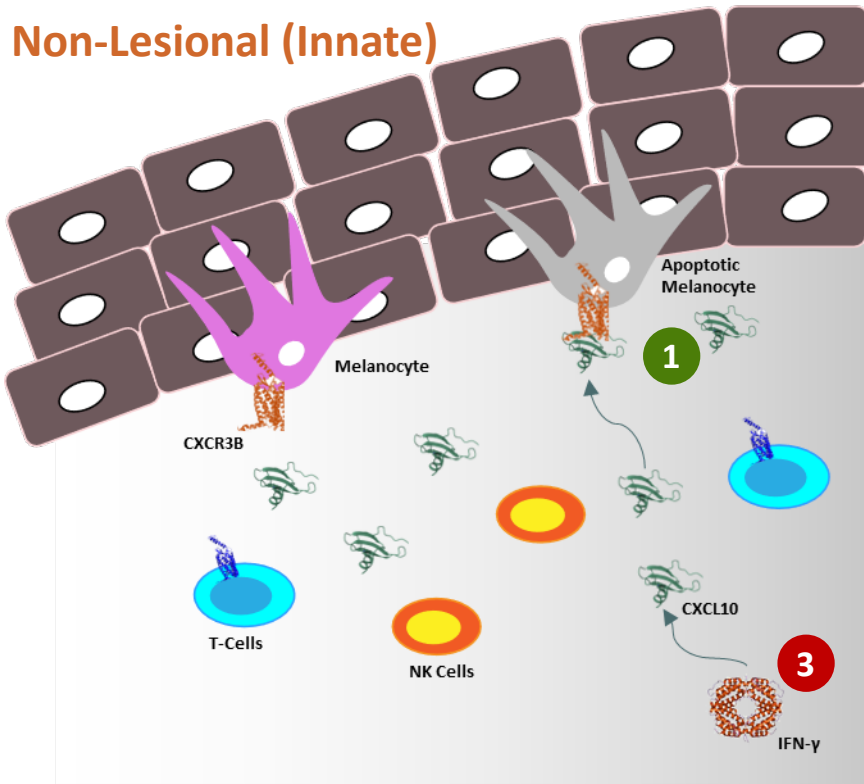
Villaris is developing auremolimab, an early clinical stage mAb that blocks IL15R



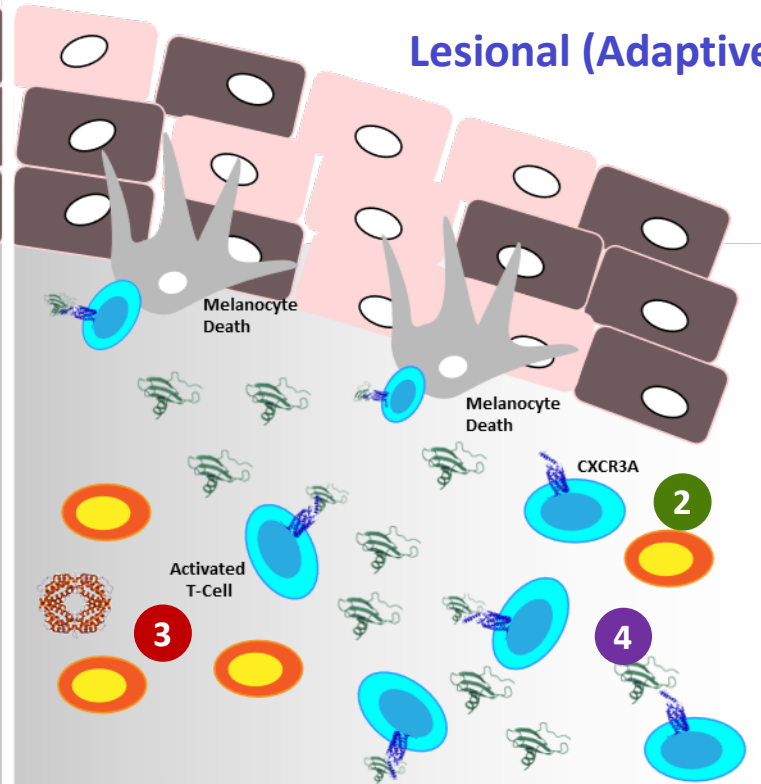
# Targeting the IFN $\gamma$ -CXCL10-CXCR3 Chemokine Axis

EB06 is an anti-CXCL10 Monoclonal Antibody that Can Act on Different Stages of Vitiligo

## Non-Lesional (Innate)



## Lesional (Adaptive)



EB06 inhibits:

**Edesa Biotech™**

- 1 CXCL10/CXC3B-mediated melanocyte apoptosis and antigen presentation
- 2 CXCL10/CXCR3A-mediated trafficking of anti-melanocytic CD8+ T cells to the epidermis



Opzelura™ (ruxolitinib) interferes:

- 3 with the JAK-STAT signaling that leads to production of CXCL9/10.



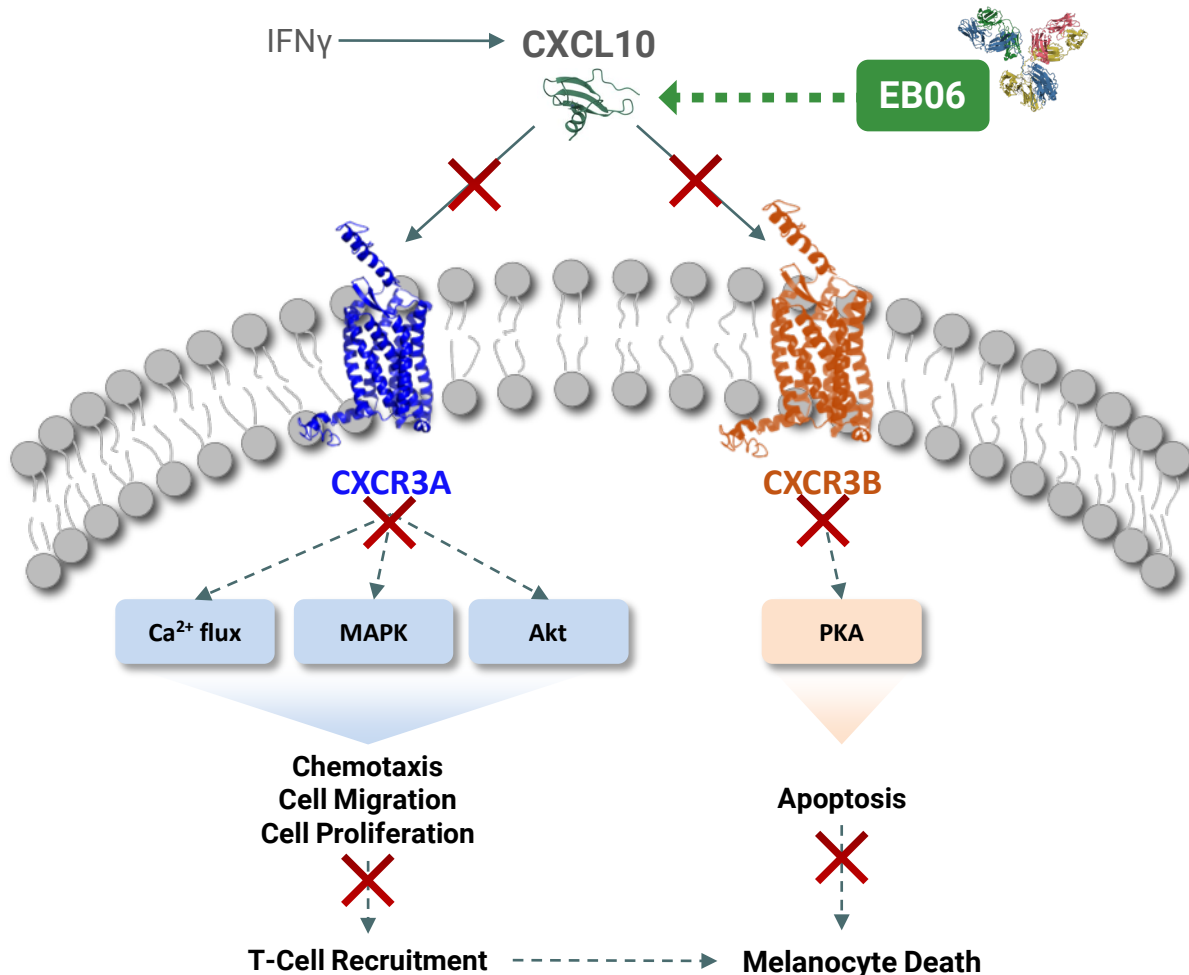
Auremolimab blocks:

- 4 IL15R leading to depletion of local effector T-cells.

Villarix was acquired by Incyte in late 2022 for up to \$1.36 billion, including \$70 million upfront.

# CXCL10 Therapeutic Potential

Therapeutically Targeting - Substantiated in Preclinical Studies



1

## Melanocyte Apoptosis

CXCL10/CXC3B mediates melanocyte apoptosis and activates anti-melanocytic CD8+ T-cells via CXCR3A

2

## Knockout Mice

CXCL10 -/- mice do not develop vitiligo

3

## Reverse Depigmentation

Anti-CXCL10 Ig in mice results in repigmentation of mice with vitiligo

4

## Patient Samples

CXCL10 is predictive of disease progression and severity

# EB06: Anti-CXCL10 Monoclonal Antibody

## Summary and Next Steps



**Targeted Mechanism of Action**  
Binds free and bound CXCL10



**65 Subjects dosed**  
No Significant AEs



**Biological Activity**  
Demonstrated



**Phase 2 Ready**  
CTA Approved



**Manufacturing**  
Leading CDMO

### NEXT STEPS

Reaching IND for submission to FDA

CRO identified and ready to be initiated

Finalizing manufacturing campaign plans with a leading global manufacturer

# Phase 2 Proof of Concept

## Moderate to Severe Non-Segmental (Generalized) Vitiligo

<b>Status</b>	CTA approved & IND being prepared
<b>Subjects</b>	Total of 153 evaluable patients randomized 1:1:1 (EB06, 10mg/kg: EB06, 20mg/kg: Placebo) across up to 25 study centers in US and Canada
<b>Treatment Period</b>	EB06 or placebo will be administered via IV every two weeks for up to 24 weeks, followed by a 12 week follow up period.
<b>Primary Endpoint</b>	Proportion of patients achieving F-VASI50 at week 24
<b>Secondary Endpoints</b>	Endpoints based on F-VASI50 and F-VASI75, mean % change in F-VASI, same for T-VASI and others  Number of treatment-emergent adverse events and serious adverse events.

# Recent Transactions in Vitiligo Space



## Incyte Announces Agreement To Acquire Medicxi-Backed Villar Therapeutics And Auremolimab (VM6), An Anti-IL-15R $\beta$ Monoclonal Antibody

- Stage of Development When Acquired: Preclinical - Monoclonal Antibody

*\$70 million, with potential for up to \$1.36 billion in additional milestone payments*



## VYNE Therapeutics Announces Private Placement of \$88 Million

Transaction provides \$88 million to fund VYNE's clinical development programs for VYN201 and VYN202

- Stage of Development: Phase 2 ready – Topical NCE (small molecule)



# Danilumuromer

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## **First-in-Class sPLA2 Inhibitor**

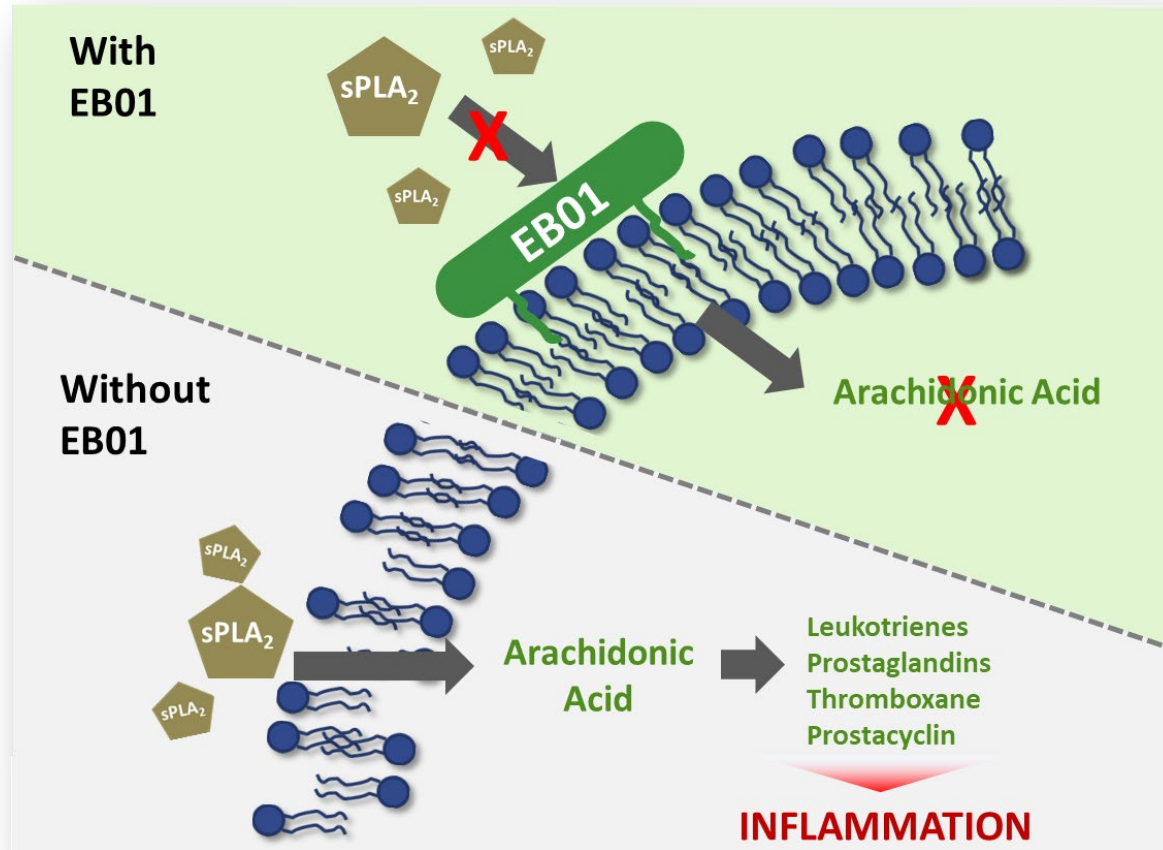
Lead Indication: ACD

Status: Topline Results Available



# Daniluromer (EB01): Treating Chronic Inflammation

Without the Safety Concerns of Current Therapies



## Inhibiting the Inflammation Cascade

- sPLA2 inhibitors are designed to inhibit the inflammatory process at its inception
- Exerts its anti-inflammatory activity upstream of currently approved NSAIDs
- Positive efficacy and safety data from two clinical studies

## Target Product Profile of EB01

- Non-Steroidal Rx for the treatment of ACD
- Alternative to corticosteroids for chronic patients

**Physicians strongly desire additional treatment options, especially for hands and face\***

- Non-steroidal approach would positively impact their practices

# Allergic Contact Dermatitis (ACD)

The Leading Occupational Health Issue Related to Dermatology



ACD is a Type IV Hypersensitivity Reaction

- > Immune system sensitized following initial contact with allergen
- > Subsequent contact results in cell-mediated allergic response at the point of contact
- > Often highly visible on face & hands

## ACD Represents a Significant Unmet Need

**3,000+**

Contact Allergens

**70%**

Unable to fully avoid allergen

**0**

No Known Labelled Drugs

Adversely impacts both employees and employers

- Loss of productivity
- Complexity of mitigation
- Lost income & disability claims

Corticosteroids and immunomodulators have safety concerns and side effects

# Significant Number of Patients with Chronic ACD

**\$4.7B**

## Total Addressable Market Opportunity

7 major markets (US, UK, Germany, France, Spain, Italy, Japan) and Canada<sup>1</sup>

**30M**

Patients with ACD across 7 major markets (US, 5EU, Japan) and Canada

**40%**

Patients with chronic exposure or frequent recurring exposure to allergen<sup>1</sup>

**5M**

Addressable patient population

“

Physicians strongly desire additional treatment options, especially for hands and face<sup>2</sup>

*“ACD...can make you quit your job.”*

*“Maybe topical steroids help a little but I almost never use them”*

*“The burden of dermatitis is greater than that of psoriasis”*

*“Topicals are easier to use and they are a safer option than oral medications.”*

# EB01 Market Positioning

Edesa's Cream is Being Developed to Address a Significant Unmet Need that Exists for Chronic ACD Patients

	Corticosteroids	TCIs	EB01
Viable for acute ACD patients	✓	✓	✓
Viable for chronic ACD patients	✗	✗	✓
Safe for long term use	✗	✗	✓
No boxed warnings	✓	✗	✓
Clinical data specific to indication	✗	✗	✓

## Topical EB01 Cream



Positioned to be a **leading therapy option** for chronic, moderate to severe ACD patients.

# Confirmatory Phase 2B Design

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## Protocol

210 total subjects  
Moderate-to-severe chronic ACD  
Double blind, placebo-controlled protocol  
28-day treatment with topical EB01 cream

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## Dose-Ranging

Determine the Lowest Efficacious Dose

EB01 Cream 0.2%  
EB01 Cream 1.0%  
EB01 Cream 2.0%

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## Multiple endpoints designed for flexibility with Phase 3 design and regulatory review

Mean % change from baseline in CDSI\*  
Safety  
ISGA\* (secondary endpoint)

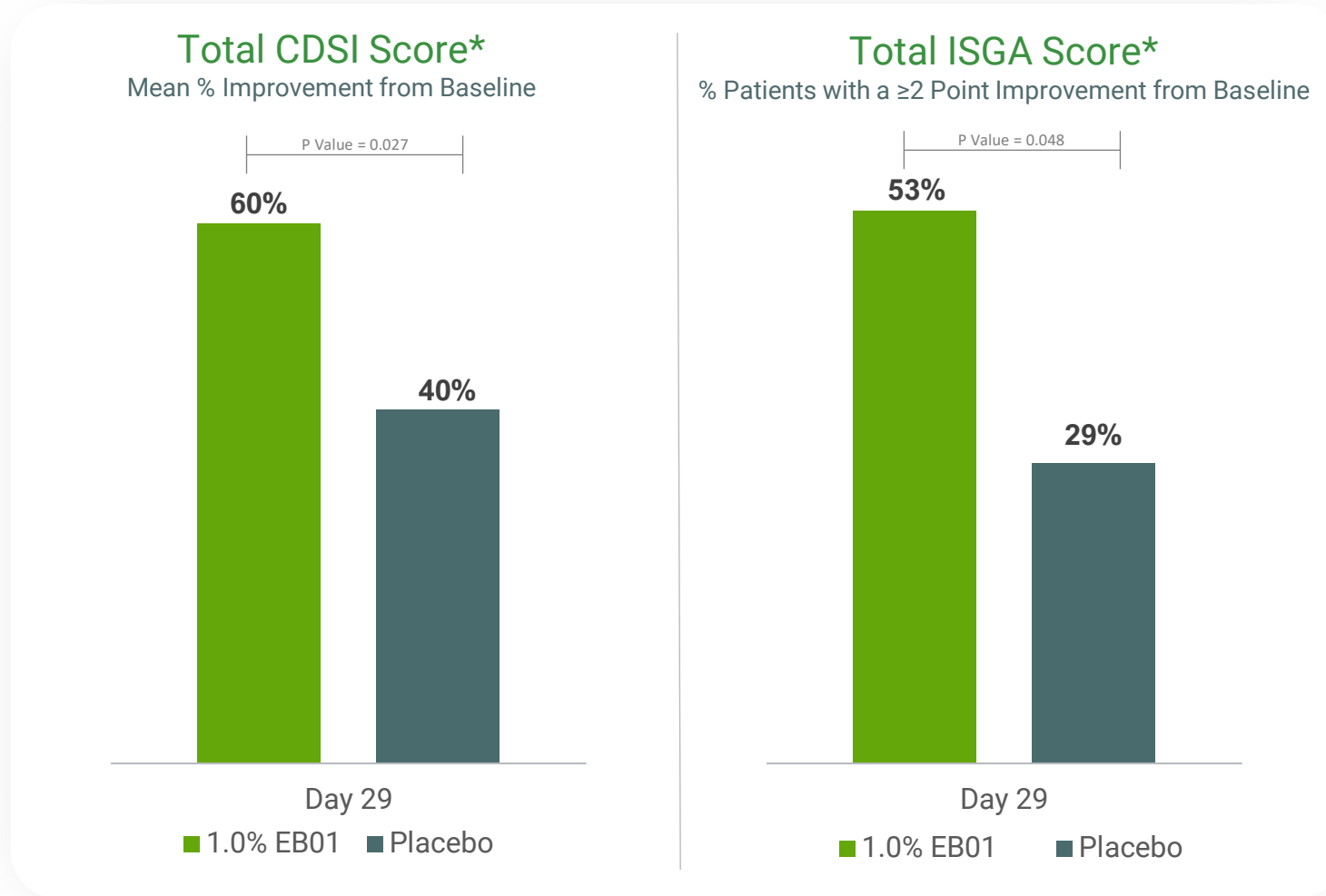
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Contact Dermatitis Severity Index (CDSI)

Success on the Investigator's Static Global Assessment (ISGA) is defined as a 2-pt reduction and score indicating clear/almost-clear skin

# Phase 2B Results - – Composite CDSI and ISGA Scores

1.0% EB01 Met Primary Endpoint and a Key Secondary Endpoint with Statistical Significance



## Summary of Results

**Efficacy:** 1.0% EB01-treated patients demonstrated a relative improvement of >50% (CDSI) and >80% (ISGA) over placebo/vehicle.

### Additional Signals:

Body Surface Area of 1.0% EB01-treated lesions was reduced by 42.1% compared to 8.8% for placebo/vehicle (p=0.054).

Reduction for each component symptom of the CDSI:

- Redness (50% EB01 vs. 35.4% placebo; p=0.17)
- Pruritis (60.5% EB01 vs. 41.3% placebo; p=0.06)
- Fissures (63.1% EB01 vs. 44.3% placebo; p=0.02)
- Scaling (58.3% EB01 vs. 42.9% placebo; p=0.36)
- Dryness (62.9% EB01 vs. 35.9% placebo; p=0.02)

**1.0% EB01 was Identified as Lowest Efficacious Dose:**

**Safety:** No serious treatment-related adverse events were reported across all concentrations.

\* Intention to Treat (ITT) population; statistical analysis based on last observation carried forward (LOCF). Placebo (n=84); 1.0% EB01 Cream (n=19). Contact Dermatitis Severity Index (CDSI) at Day 29. Success on the Investigator's Static Global Assessment (ISGA) is defined as a 2-pt reduction and score indicating clear/almost-clear skin. Topline study data are preliminary and subject to change.

# Proposed Global Phase 3 Moderate to Severe Chronic ACD

Two Replicate Pivotal Phase Studies Will Likely Be Required\*

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## Protocol

~500 total subjects  
Moderate-to-severe chronic ACD  
Double blind, placebo-controlled protocol  
28-day treatment with topical EB01 cream

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## Dose

EB01 Cream 1.0%

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## Primary Endpoint

ISGA Composite\*

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## Secondary Endpoint

Mean % change from baseline in CDSI\*  
Safety

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Contact Dermatitis Severity Index (CDSI)

Success on the Investigator's Static Global Assessment (ISGA) is defined as a 2-pt reduction and score indicating clear/almost-clear skin

\* Based on comparable dermatological Phase 3 programs. End of Phase 2 meeting to determine requirements



# Experienced Leadership Team

## Pharmaceutical Pipelines, Corporate Development & Strategic Transactions

### Executive Management Team

**Par Nijhawan, MD, FRCPC, AGAF**  
CEO and Board Director

**Gary Koppenjan**  
VP, Corporate Affairs

**Michael Brooks, PhD**  
President

**Blair Gordon, PhD**  
VP, Research & Development

**Stephen Lemieux, CPA**  
Chief Financial Officer

### Select Strategic Transaction Experience of Leadership Team

 EXZELL PHARMA

Acquisition by  
Biolab Pharma 2022

 Stellar  
BIOTECHNOLOGIES

Reverse Acquisition  
by Edesa 2019

 MFI  
Medical Futures Inc.

Acquisition by Tribute  
Pharma 2015

 LIGHTCHAIN  
BIOSCIENCE

In-License  
2020

 Yissum  
Hebrew University Technology Transfer

In-License  
2016

 pharma  
science

Development/  
Out-license 2017

 MATRIVAX

Out-License  
2017

 CERES

Tender Offer by Land  
O'Lakes 2016

 PENNSAID

Sold U.S. Rights  
2014

### Independent Directors

**Joan Chypyha**  
 Alto  
Pharma

**Patrick Marshall**  
 Jouleia

**Sean MacDonald**  
 DOMAIN  
THERAPEUTICS

**Frank Oakes**  
 Stellar  
BIOTECHNOLOGIES

**Charles Olson**  
 Dendreon

**Carlo Sistilli, CPA, CMA**  
 ARISTA  
HOMES

# Clinical Summary

## First-in-Class Therapeutics for Immuno-Inflammatory Diseases



### **EB05 (paridiprubart)**

Validated Phase 3 Program with Govt Funding



### **EB01 (daniluromer)**

Phase 3 Ready w/ Partnering in Process



### **EB06 – Vitiligo – Phase 2 Ready**

Significant Transactions in this Therapeutic Area and Pathway



### **EB07 – Fibrosis**

Phase 2 Ready Asset





[www.EdesaBiotech.com](http://www.EdesaBiotech.com)  
[investors@edesabiotech.com](mailto:investors@edesabiotech.com)

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**Nasdaq**  
**LISTED**