

**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	Anti-TLR4 (mAb)	<b>EB05</b> Paridiprubart	ARDS - Covid-19					Enrolling	Ph3 funding from the Canadian Govt; Fast Track by the FDA
		<b>EB05</b> Paridiprubart	ARDS - General					To be initiated	Planning in progress
		<b>EB07</b> Paridiprubart	Pulmonary Fibrosis					IND in progress	Ph2 study prep in progress
Dermatology	sPLA2 Inhibitor (Small Molecule)	<b>EB01</b> Daniluromer	Allergic Contact Dermatitis (ACD)					Ph3-ready	Final results released; Ph3 partnering discussions in progress
	Anti-CXCL10 (mAb)	EB06	Vitiligo					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

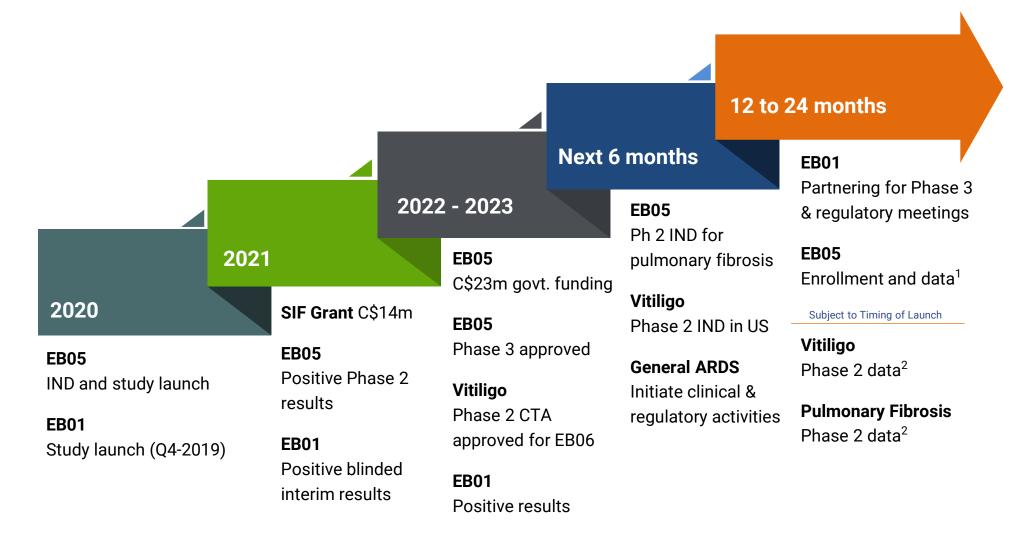
Accessible with focused commercial organization (North America)

Synergies with pipelines/interests of potential strategic partners





#### Milestone-Rich Clinical Calendar





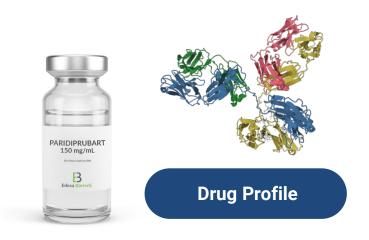
# **EB05**

Paridiprubart for Acute and Chronic Respiratory Diseases



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

First-in-Class mAb that Specifically Blocks TLR4 Signalling

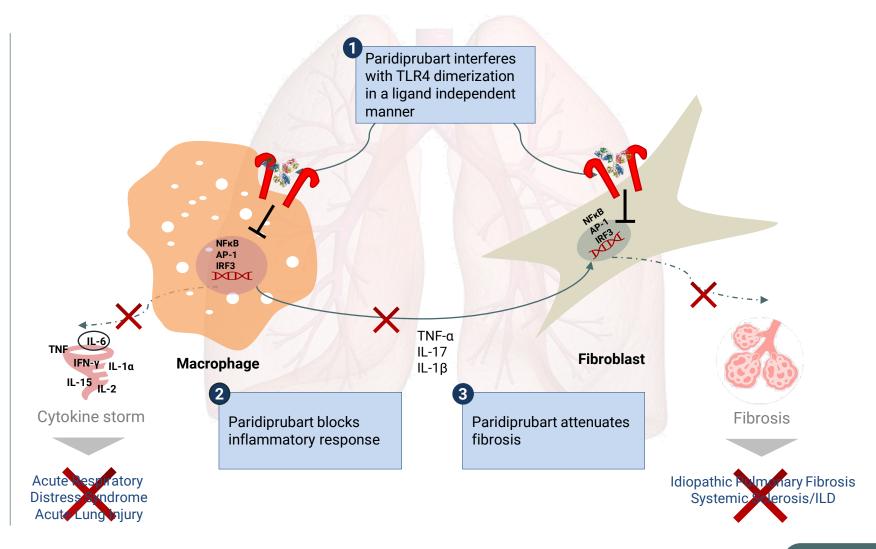


A humanized IgG1k monoclonal antibody

Binds to TLR4 with high affinity

Extensive preclinical and clinical development: 600+ subjects

Multiple manuf. runs by a leading CDMO





## 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.4

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** 

Edesa Biotech



Endemic Covid-19 + other pathogens



Increasing awareness and better diagnosis



Ageing population



Increasing incidence of comorbidities/risk factors3

Bellani et at (2016), JAMA;

FAIR Health, Total Treatment Cost, Sept 2021; average allowed and charged cost per complex COVID-19 patient in the US.

Pfortmueller et al (2021), Best Pract Res Clin Anaesthesiol

Company estimate

## **Phase 2 Clinical Efficacy Demonstrated**

Statistically Significant Mortality Trend in Critical Patients

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

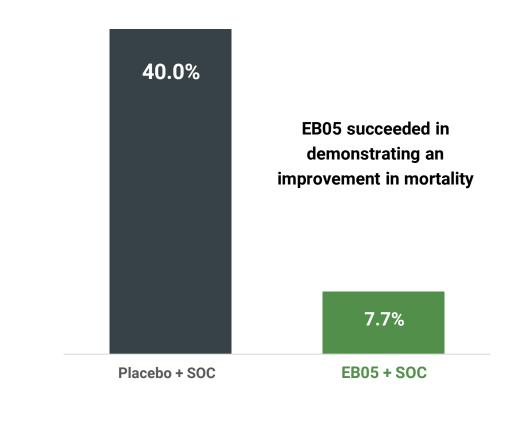
- Strong efficacy signal for 28-day mortality
- Favorable safety analysis of ~360 subjects

#### **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)





Study Funding Provided by the Strategic Innovation Fund

# **EB07**

Paridiprubart for Pulmonary Fibrosis



#### **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)

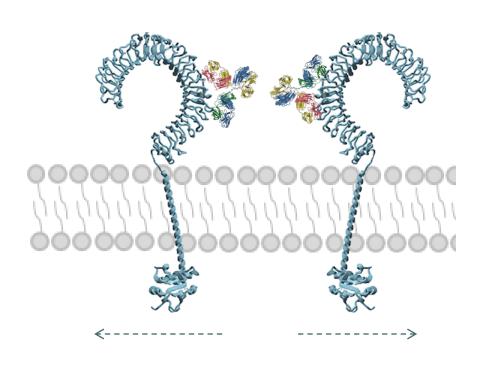






# **TLR4's Therapeutic Potential in Fibrotic Diseases**

**Summary of Preclinical Evidence** 



- TLR4 knock-out animal models display attenuated fibrosis
- TLR4 antagonists lead to reduced fibrosis in animal models

- TLR4 antagonists can reverse fibrosis in animal models
- TLR4 agonists are predictors of disease progression and severity

## **Leveraging Existing Work from the ARDS Program**

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 multidose (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

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



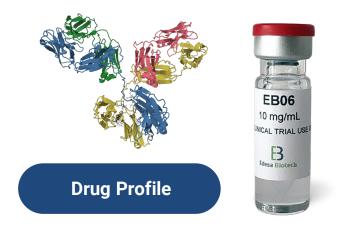
# EB06 - Vitiligo

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



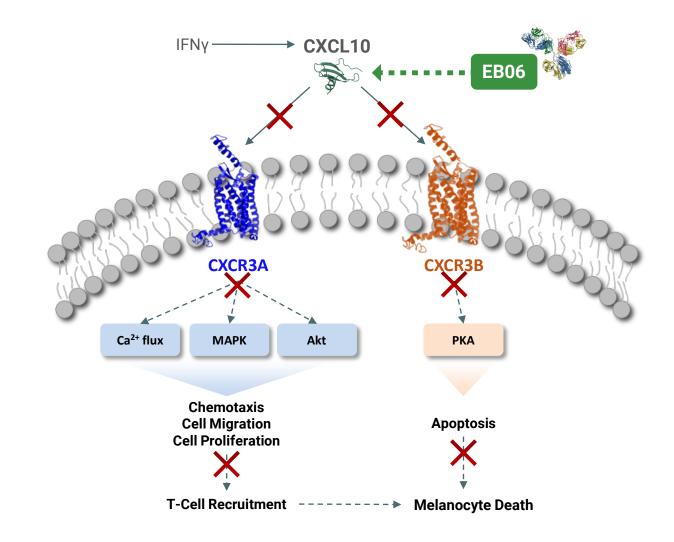
A humanized IgG1k monoclonal antibody

Binds specifically to CXCL10 with high affinity

65 patients dosed

Sequesters and renders CXCL10 inactive

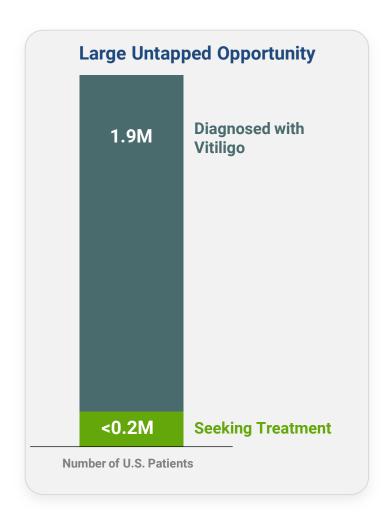
Multiple manuf. runs by a leading CDMO





## **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

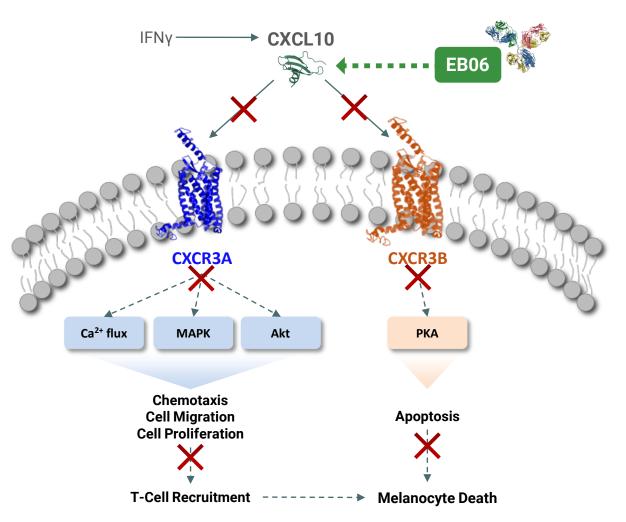


Villaris was acquired by Incyte in late 2022 for up to \$1.36B, including \$70M upfront

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

### **CXCL10 Therapeutic Potential**

#### Therapeutically Targeting - Substantiated in Preclinical Studies



1 Melanocyte Apoptosis

CXCL10/CXC3B mediates melanocyte apoptosis

CXCL10 -/- mice do not develop vitiligo

Reverse Depigmentation

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

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**

Readying IND for submission to FDA

CRO identified and ready to be initiated

Finalizing manufacturing campaign plans with a leading global manufacturer

# **Daniluromer**

First-in-Class sPLA2 Inhibitor

Lead Indication: ACD

Status: Topline Results Available



## **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 70%

U

Contact Allergens Unable to fully avoid allergen

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**



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."

\$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



### **EB01 Market Positioning**

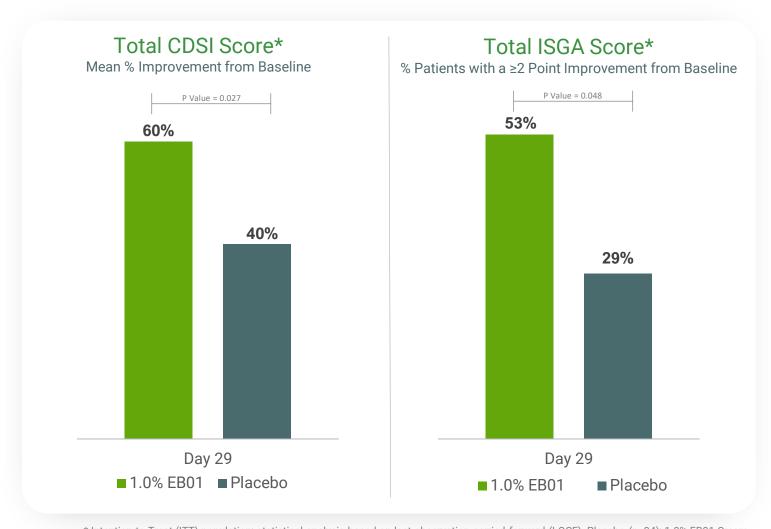
Edesa's Cream is Being Developed to Address a Significant Unmet Need that Exists for Chronic ACD Patients

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



## 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.

Edesa Biotech

<sup>\*</sup> 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.

### **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



Acquisition by Biolab Pharma 2022



Reverse Acquisition by Edesa 2019



Acquisition by Tribute
Pharma 2015



In-License 2020



In-License 2016



Development/ Out-license 2017



Out-License 2017



Tender Offer by Land O'Lakes 2016



Sold U.S. Rights 2014

#### **Independent Directors**



**Patrick Marshall** 



Sean MacDonald



Frank Oakes



**Charles Olson** 



Carlo Sistilli, CPA, CMA





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