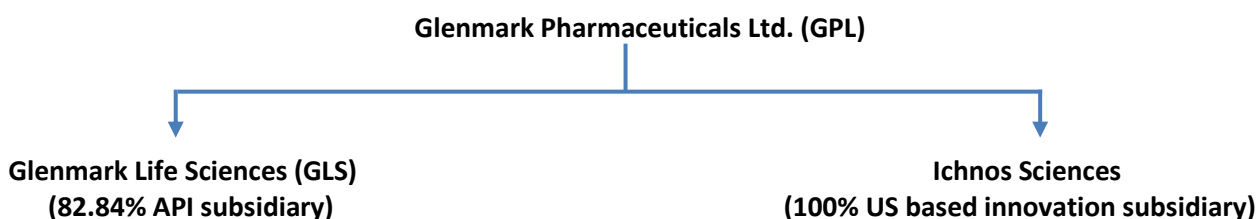


**Management Discussion & Analysis for the First Quarter of FY 2022-23**

**Glenmark operates its businesses through three separate entities**



Each of these three entities operate independently with separate Management Teams and Board of Directors.

**Revenue Figures for Glenmark Pharmaceuticals Ltd. (Consolidated)**

*(Rs. In Millions)*

	For the first quarter ended June 30		
	FY 2022-23	FY 2021-22	Growth (%)
<b>India</b>	10,352	12,250	-15.5%
<b>North America</b>	6,628	7,878	-15.9%
<b>Europe</b>	3,300	3,059	7.9%
<b>Rest of the World<sup>1</sup></b>	4,226	3,360	25.8%
<b>API</b>	3,251	3,040	6.9%
<b>Total</b>	<b>27,757</b>	<b>29,587</b>	<b>-6.2%</b>
<b>Other Revenue</b>	16	62	-73.9%
<b>Consolidated Revenue</b>	<b>27,773</b>	<b>29,649</b>	<b>-6.3%</b>

1. Asia, Middle East and Africa, RCIS and LATAM
2. Average conversion rate in 3M FY 2022-23 considered as INR 76.98 / USD 1.00  
Average conversion rate in 3M FY 2021-22 considered as INR 73.68 / USD 1.00  
USD figures are only indicative

## Review of Operations for the quarter ended June 30, 2022

For the first quarter of FY 2022-23, Glenmark's consolidated revenues from operations was at Rs. 27,773 Mn (USD 360.8 Mn) as against Rs. 29,649 Mn (USD 402.4 Mn) in the corresponding quarter last year, recording a decrease of -6.3%. Excluding global sales of Covid-related products in the first quarter of FY22, the year-on-year growth of the base business in the current financial year was 10.4%.

### **GLENMARK PHARMACEUTICALS LTD. (GPL)**

**GPL is primarily focused on building a global Generics, Specialty, and OTC business in the therapy areas of Dermatology, Respiratory and Oncology. It also has strong regional/country-specific presence in other therapeutic areas like diabetes, cardiovascular and oral contraceptives.**

#### **India**

Sales from the formulation business in India for the first quarter of FY 2022-23 was at Rs. 10,352 Mn (USD 134.5) as against Rs. 12,250 Mn (USD 166.3 Mn) in the previous corresponding quarter, recording a decrease of -15.5%. This decline is on account of a high base due to sales of Covid-related products in Q1 FY22. The India business contribution was at 37.3% of the total revenues in Q1 FY23 compared to 41.3% in Q1 FY22.

As per IQVIA MAT June 2022, Glenmark's India formulation business is ranked 14<sup>th</sup> with a market share of 2.17%. During the quarter, Glenmark's India business further strengthened its position in its core therapy areas such as Cardiac and Anti-diabetic in terms of market share. As per IQVIA MAT June 2022, the Cardiac segment market share increased to 5.18% compared to 4.64% last year while the Anti-diabetic segment market share increased to 1.81% compared to 1.78% last year. The derma segment market share changed from 8.21% to 8.16% and the respiratory segment market share changed from 5.24% to 5.19% in Q1 FY23.

As per IQVIA MAT June 2022, the company was ranked 2<sup>nd</sup> in Derma segment, 4<sup>th</sup> in respiratory segment and increased its ranking to 5<sup>th</sup> from 6<sup>th</sup> in cardiac segment. The company has nine brands in the top IPM 300 brands in the country up from 6 brands last year on the basis of IQVIA MAT June 2022.

The company launched seven new products during the quarter, including Indamet® for the treatment of uncontrolled asthma. Glenmark is the first company in India to market this innovative fixed drug combination of Indaceterol, a long acting beta-agonist and mometasone, an inhaled corticosteroid. This launch further increases the accessibility of quality drugs for effective asthma management. The company has a healthy pipeline of differentiated products which it plans to launch in the market going forward.

## **India – Glenmark Consumer Care (GCC) Business**

GCC business recorded revenue of Rs. 647 Mn with primary sales growth of 94% YoY, driven by strong performance in the core brands such as Candid® Powder, La Shield®, and Scalpe®. La Shield and Scalpe plus registered their highest quarterly primary sales while Candid Powder maintained its dominant market leadership status and showed sharp recovery in sales during the quarter. Candid Prickly Heat Powder also had a strong start in the quarter having been launched in the latter half of the last financial year.

## **North America**

North America registered revenue from the sale of finished dosage formulations of Rs. 6,628 Mn (USD 86.1 Mn) for the first quarter of FY23 as against revenue of Rs. 7,878 Mn (USD 106.9 Mn) for the previous corresponding quarter, recording a decline of -15.9%. North America business contributed 23.9% to the consolidated sales in Q1 FY23, compared to 26.6% in Q1 FY22.

In the first quarter of fiscal year 2022-23, Glenmark was granted PAS final approval and launched Abiraterone Acetate Tablets USP, 500 mg. In addition, Glenmark launched the previously approved product Ezetimibe Tablets USP. The Company also received Tentative Approval for Calcipotriene and Betamethasone Dipropionate Foam, 0.005%|0.064%. Glenmark plans to file one application in the forthcoming quarter, as well as a Prior Approval Supplement to expand the OTC portfolio which is complemented by the acquisition of 5 approved OTC ANDAs from Wockhardt Limited. The company plans to file 12-15 ANDAs in FY23.

Glenmark's marketing portfolio through June 30, 2022 consists of 176 generic products authorized for distribution in the U.S. market. The Company currently has 48 applications pending in various stages of the approval process with the US FDA, of which 20 are Paragraph IV applications.

## **Europe**

Glenmark Europe operations' revenue for the first quarter of FY 2022-23 was at Rs. 3,300 Mn (USD 42.9 Mn) as against Rs. 3,059 Mn (USD 41.5 Mn) recording a growth of 7.9%. Europe business contributed 11.9% of the total revenues in Q1 FY23 compared to 10.3% in Q1 FY22.

The company witnessed steady growth in both its key markets of Western Europe and Central & Eastern Europe during the quarter. Growth in Western Europe remained robust, led by double digit growth in key markets like the Netherlands, Spain and the Nordic countries. The Central & Eastern European region maintained its strong growth trajectory especially in markets like Poland and the Czech Republic. Overall, the company launched two products in the Czech Republic and one product each in the UK, the Netherlands, Germany and Spain respectively during the quarter. Glenmark's respiratory portfolio

continues to do well across all markets in Europe.

Glenmark has a comprehensive plan to grow its European business going ahead, including geographical expansion in new markets and expansion of its product portfolio to leverage launches in key therapeutic segments like respiratory and dermatology.

### **Asia, MEA, LATAM and RCIS Region (Rest of the World)**

For the first quarter of FY 2022-23, revenue from the ROW region was Rs. 4,226 Mn (USD 54.9 Mn) as against Rs. 3,360 Mn (USD 45.6 Mn) for the previous corresponding quarter, recording a growth of 25.8%. ROW business contributed 15.2% of the total revenues in Q1 FY23 compared to 11.3% in Q1 FY22.

The challenging conditions in Russia, as a consequence of the economic sanctions led to erratic consumer behavior in March, which impacted the sales in Q1 FY23. Secondary sales de-grew 11% YoY in value terms during the current quarter. The company recently received approval for Dimetindene Gel which strengthens the derma portfolio in the region. Also Ryaltris received approval for an additional indication and the overall response to the product has been very encouraging in the market. The company has various strategic initiatives to strengthen the respiratory franchise in the region going ahead.

Asia region continued its strong performance led by positive momentum in key markets like the Philippines and Malaysia where secondary sales grew 42% YoY and 41% YoY respectively. The company has extensive plans to strengthen its respiratory franchise with the launch of Ryaltris in multiple markets in FY23.

The Middle East and Africa region recorded secondary sales growth of 19% YoY during the quarter, with positive growth across major markets like, South Africa, Saudi Arabia and the UAE. The company expects the growth momentum to continue for the rest of the year.

LATAM witnessed a growth of 35% as a region. Markets such as Mexico, Colombia and Ecuador witnessed a strong momentum in the respiratory business on the back of prescription-generated demand, whereas growth in Argentina was driven mainly by oncology. Glenmark's Brazil business also delivered growth on the base product portfolio.

### **Respiratory – Creating Global Scale**

Following are the key business updates for Glenmark's global respiratory business in Q1 FY23:

#### **Ryaltris™**

- During the first quarter, Glenmark received Marketing Authorization (MA) grants for Ryaltris in

Singapore and Bahrain. The company is awaiting regulatory approvals for its filings in Canada, Brazil, Malaysia, and several other emerging markets.

- Glenmark's partner in the EU, Menarini, initiated the commercial launch in Ireland in the first quarter, and intends to launch the product in additional European markets in the coming quarters.
- Ryaltris sales continued to grow in Australia, the UK, Czech Republic, Poland, Russia, Ukraine, Uzbekistan, South Africa, the Philippines, Peru and Ecuador. Glenmark is also working with its partner in South Korea, Yuhan Corporation, to enable commercial launch in Q2 FY23. Glenmark's partner in Mainland China, Grand Pharmaceutical (China) Co. Ltd., initiated enrollment in the Phase 3 study in China in April 2022.
- Glenmark's exclusive partner for Ryaltris in the US, Hikma Specialty USA Inc., is preparing for product launch post receiving US FDA approval

### **Other key products**

- Clinical trial ongoing for Flovent pMDI; Expect to file in CY23
- Plan to file at least one more respiratory pMDI in the US in CY23 and continue filing momentum beyond FY24
- Launched Indamet for the treatment of uncontrolled asthma in India
- Europe respiratory franchise of Soprobe<sup>®</sup> (Beclomethasone MDI), Salmex (Salmeterol/Fluticasone DPI), Tiogiva<sup>®</sup>/Tavulus<sup>®</sup> (Tiotropium DPI) and Ryaltris<sup>™</sup> (olopatadine/mometasone nasal spray) also shaping up well in both Western Europe and Central & Eastern Europe

### **Innovative R&D Pipeline**

#### **GRC 17536**

GRC 17536 (TRPA1 antagonist) is the company's pain pipeline asset being developed as an orally administered treatment in patients with painful diabetic peripheral neuropathy. GLP toxicology studies for metabolite qualification were completed last year. The GRC 17536 Phase 2b study was initiated in Q2 FY22 and is currently ongoing in India with interim data for futility analyses expected by Q2 FY23

#### **GRC 54276**

GRC 54276 (HPK1 Inhibitor) is the company's oncology pipeline asset being developed as an orally administered IO-adjuvant treatment for patients with solid tumors in oncology. A Phase 1 study is currently underway, and Glenmark is targeting to file for a US IND in H2 FY23

#### **GBR 310**

Glenmark had announced successful Phase 1 results for GBR 310 that suggest similarity in pharmacokinetic, pharmacodynamic, safety and immunogenicity profiles between GBR 310, and the reference product, Omalizumab, marketed in the US under the brand name Xolair®. Glenmark is in discussion with potential partners to out-license the product.

## **GRC 39815**

GRC 39815 (RORγt inhibitor) is the company's respiratory pipeline asset being developed as an inhaled therapy for treatment of mild to moderate Chronic Obstructive Pulmonary Disorder (COPD), currently under Phase 1 clinical development in the US.

## **GLENMARK LIFE SCIENCES LTD. (GLS)**

**Glenmark Life Sciences primarily includes manufacturing and marketing of Active Pharmaceutical Ingredient (API) products across all major markets globally. It also includes captive sales (i.e. use of API by GPL for its own formulations).**

Revenues from operations including captive sales were Rs. 4,899 Mn as against Rs. 5,249 Mn, recording a YoY decline of -6.7% due to high base of Covid products sales last year. During Q1 FY23, regulated markets contribution remains stable at ~72% with flattish growth YoY. Emerging markets witnessed growth of 23.7% YoY excluding Covid products. The Company has received Environmental Clearance for the installation of 1,000 KL capacity for the planned greenfield site at Chincholi Industrial Area, Solapur and construction work will begin in the current financial year.

External sales for Glenmark Life Sciences in Q1 FY23 were at Rs. 3,251 Mn (USD 42.2 Mn) as against Rs. 3,040 Mn (USD 41.3 Mn) in Q1 FY22, recording a growth of 6.9% YoY.

For further updates on the organization, please log on to [www.glenmarklifesciences.com](http://www.glenmarklifesciences.com).

## **ICHNOS SCIENCES Inc.**

Glenmark has invested Rs. 1,682 Mn (USD 21.8 Mn) in the first quarter of FY 2022-23 compared to Rs. 1,617 Mn (USD 21.9 Mn) in the corresponding quarter last year.

For further updates on the pipeline and the organization, please log on to [www.ichnossciences.com](http://www.ichnossciences.com).

The pipeline update for the first quarter of FY23 is published on this website.

## **KEY OBJECTIVES FOR FY23**

- Revenue growth of 6-8% during the year
- Sustain EBITDA margin performance at similar levels of FY22
- Capex of Rs. 7-8 Bn
- Strategic priority to enhance free cash generation for further debt reduction
- Close 1-2 out-licensing agreements in innovation pipeline

## **Disclaimer**

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# ICHNOS SCIENCES INC.



















## AUGUST 2022 UPDATE

### ABOUT ICHNOS

Ichnos Sciences aims to shift the way the world thinks about innovation in medicine by developing potentially transformative biologic treatments in immuno-oncology. The company, currently a subsidiary of Glenmark Holding, SA, plans to pursue external financing following achievement of clinical proof of concept for its lead assets.

Headquartered in New York City, Ichnos has discovery and manufacturing operations at two sites in Switzerland. As a fully integrated biotechnology company with approximately 225 employees, Ichnos has strong capabilities in research, antibody engineering, CMC, and clinical development of biotechnologies.

Ichnos is guided by an accomplished management team with experience developing immune cell engagers within the biopharmaceuticals industry, and is led by Cyril Konto, M.D., President and Chief Executive Officer.

<p><b>CYRIL KONTO, M.D.</b> President and Chief Executive Officer</p> <p>  </p>	<p><b>ERIC J. FELDMAN, M.D.</b> Chief Medical Officer</p> <p> </p>	<p><b>ROBERTO GIOVANNINI, Ph.D.</b> Chief Process and Manufacturing Officer</p> <p> </p>
<p><b>PATRICIA JAQUET</b> Global Head of Human Resources</p> <p></p>	<p><b>GRACE MAGUIRE</b> Head of Communications and Corporate Affairs</p> <p> </p>	<p><b>ASHOK MARÍN</b> General Counsel</p> <p> </p>
<p><b>MICHAEL D. PRICE</b> Chief Financial Officer</p> <p> </p>	<p><b>EUGENE ZHUKOVSKY, Ph.D.</b> Chief Scientific Officer</p> <p>   </p>	



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The proprietary BEAT<sup>®</sup> technology platform<sup>1</sup> is the basis for Ichnos' clinical-stage oncology pipeline. Using this technology, coupled with the proprietary common light chain library, the company is developing novel multispecific immune cell engagers and modulators, with the goal of realizing its mission to provide breakthrough, potentially curative therapies that may extend and improve lives, writing a new chapter in healthcare.

## ONCOLOGY PIPELINE

The first wave of Ichnos' multispecific antibody pipeline consists of five programs targeting a range of hematologic malignancies and solid tumor indications through engagement of a broad spectrum of immune cells. The most advanced program is ISB 1342, a clinical-stage, potentially first-in-class bispecific antibody targeting CD38 and CD3, which is in Phase 1 for the treatment of relapsed/refractory multiple myeloma. A Phase 1/2 dose escalation/expansion study for ISB 1442, Ichnos' 2+1 biparatopic bispecific antibody targeting CD38 and CD47, is expected to begin dosing patients during the third quarter of calendar year 2022.

MOLECULE MECHANISM/CLASS	PHASE/STATUS	LEAD INDICATION
ISB 1342 CD38 x CD3 BEAT <sup>®</sup> 1.0 bispecific antibody	Phase 1	Relapsed/Refractory Multiple Myeloma; T-ALL is under consideration
ISB 1442 CD38 x CD47 BEAT <sup>®</sup> 2.0 bispecific antibody	Phase 1	Relapsed/Refractory Multiple Myeloma; AML and T-ALL are under consideration
ISB 2001 BCMA x CD38 x CD3 TREAT <sup>™2</sup> trispecific antibody	IND-Enabling Studies	Relapsed/Refractory Multiple Myeloma
ISB 2004 BEAT <sup>®</sup> 2.0 bispecific antibody	Discovery	Hematologic Malignancies/ Solid Tumors
TREAT <sup>™</sup> trispecific platform (formerly ISB 2005)	Discovery	Solid Tumors

<sup>1</sup> Bispecific Engagement by Antibodies based on the TCR

<sup>2</sup> Trispecific Engagement by Antibodies based on the TCR



## OVERVIEW OF SELECT ONCOLOGY DRUG PRODUCT CANDIDATES

### ISB 1342 (CD38 X CD3 BISPECIFIC ANTIBODY)

- A Phase 1, open-label, dose-escalation, first-in-human study of ISB 1342 in patients with relapsed/refractory multiple myeloma is ongoing.
  - + Enrollment of patients receiving a weekly dosing regimen is ongoing.
  - + Number of sites participating in the study was expanded at the end of calendar year 2021 to enhance enrollment. New locations in the U.S. were added and 11 sites were opened for enrollment in France and are now recruiting subjects.
  - + Clinical proof of concept in the ongoing study is anticipated in the second half of calendar year 2022.
- The primary objectives of the study are to:
  - + Determine maximum tolerated dose and/or recommended Phase 2 dose of ISB 1342 (Part 1 dose escalation).
  - + Assess anti-myeloma activity of ISB 1342 according to the International Myeloma Working Group response criteria (Part 2 dose expansion).
- Preclinical data on ISB 1342 were presented at the 2021 ASCO Annual Meeting and EHA 2021 Virtual Congress.
- ISB 1342 was granted Orphan Drug Designation for multiple myeloma by the FDA.
- The bulk drug substance is manufactured at the Ichnos site in La Chaux-de-Fonds, Switzerland.

### ISB 1442 (CD38 X CD47 BISPECIFIC ANTIBODY)

- This first-in-class 2+1 biparatopic bispecific antibody targeting CD38 x CD47 was generated using the BEAT<sup>®</sup> 2.0 technology developed by scientists in Ichnos' laboratories in Lausanne at the Biopole life sciences campus.
- ISB 1442 is designed to kill CD38-expressing tumor cells through inhibition of the CD47-SIRP $\alpha$  axis to increase antibody-dependent cellular phagocytosis (ADCP) and enhance antibody-dependent cellular cytotoxicity through complement-dependent cytotoxicity (CDC) and antibody-dependent cell cytotoxicity (ADCC), enabled by the architecture and engineered Fc of the molecules.
- An IND was filed with the US Food and Drug Administration earlier this calendar year and was recently cleared. A Phase 1/2 first-in-human dose-finding study of ISB 1442 in relapsed/refractory multiple myeloma recently began, and the first patient is expected to be dosed during the third quarter of calendar year 2022. Ichnos plans to develop ISB 1442 in other hematologic malignancies, including acute myeloid leukemia (AML) and T-


cell acute lymphoblastic leukemia (T-ALL).

- Preclinical data on ISB 1442 were shared in an oral presentation at the 2021 American Society of Hematology Meeting on December 11, 2021. These data, which may be viewed at this [link](#), show:
  - + Higher potency in vitro for ISB 1442 relative to daratumumab in CD38 high/low tumor models as measured by a multiple antibody-dependent mechanisms of action killing assay
  - + Higher tumor growth inhibition for ISB 1442 than daratumumab in CD38 high preclinical in vivo xenograft models
  - + Low on-target off-tumor binding with ISB 1442 compared to anti-CD47 mAb (5F9), is anticipated to result in lower red blood cell depletion in clinic, and potentially a better therapeutic index than anti-CD47 bivalent monoclonal antibodies
- Additional preclinical data on ISB 1442 were presented at the [2022 American Association for Cancer Research \(AACR\) Annual Meeting in April](#) and the [European Hematology Association Meeting in June 2022](#).
- The first bulk drug substance batches to support IND filing and the ongoing Phase 1/2 dose escalation and expansion study were manufactured at the Ichnos site in La Chaux-de-Fonds, Switzerland in 2021.

## ISB 2001 TREAT™ TRISPECIFIC ANTIBODY

- ISB 2001 is the first T cell-engaging antibody that targets BCMA and CD38 on multiple myeloma cells. It is a trispecific antibody based on BEAT® 2.0 technology, a proprietary platform allowing maximal flexibility and manufacturability of full length multispecific antibodies. Additional ISB 2001 details include:
  - ISB 2001 combines three proprietary fragment antigen-binding arms, each targeting a different antigen, with one arm binding to the epsilon chain of CD3 on T cells, and the other two binding BCMA and CD38 on myeloma cells. Its Fc domain was fully silenced to suppress Fc effector functions.
  - In vitro studies showed that ISB 2001 exhibited increased killing potency of tumor cells compared to all tested antibodies that are either currently approved therapeutics for multiple myeloma or are being tested in ongoing clinical studies. In vivo studies in the multiple myeloma models also demonstrated superior potency of ISB 2001 relative to approved antibody treatments of multiple myeloma.
  - ISB 2001 redirects CD3+ T lymphocytes to kill tumor cells expressing low to high levels of both BCMA and CD38. With two different tumor-associated

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antigens instead of one, ISB 2001 has increased binding specificity to multiple myeloma cells due to enhanced avidity-based binding.

- Currently in IND-enabling studies, Ichnos intends to file a US IND for ISB 2001 in the first quarter of calendar year 2023 and is considering expansion to additional countries in parallel.
- Process development is ongoing at the Ichnos site in La Chaux-de-Fonds, Switzerland. Manufacturing of Phase 1 clinical supplies is scheduled to start in calendar year 2022.

## **AUTOIMMUNE DISEASES**

Ichnos has two monoclonal antibody drug product candidates addressing autoimmune diseases in the pipeline. In order to enhance the company's focus on oncology, future development of both assets will be overseen by out-licensing partners. The first, ISB 880, an anti-IL-1RAP antagonist, was licensed to Almirall, S.A. in December 2021. The second, ISB 830 (telazorlimab), an OX40 antagonist that completed a Phase 2b study in moderate to severe atopic dermatitis in calendar year 2021, is in partnering discussions. Both compounds have potential across a range of autoimmune diseases.



## ASSETS IN AUTOIMMUNE DISEASE

MOLECULE MECHANISM/CLASS	POTENTIAL INDICATIONS	PHASE	STATUS
ISB 880 (ALM 27134) IL-1RAP Antagonist Monoclonal Antibody	Autoimmune Diseases	Initiating Phase 1	Licensed to Almirall S.A. in December 2021. Almirall is initiating a Phase 1 study.
ISB 830 Telazorlimab OX40 Antagonist Antibody	Atopic Dermatitis	Phase 2b	Successfully completed a Phase 2b study in Atopic Dermatitis. Exploring partnership(s).
	Other autoimmune diseases, including Rheumatoid Arthritis	U.S. IND for Rheumatoid Arthritis and other autoimmune indications is active.	

### ISB 880 (IL-1RAP ANTAGONIST)



- Ichnos entered an exclusive global licensing agreement for ISB 880 in autoimmune diseases with Almirall in December 2021. Within the terms of the agreement, Almirall will assume full cost and responsibility for the global development and commercialization of the compound. Ichnos received an upfront payment of €20.8 million. The deal also includes development and commercial milestone payments and tiered royalties based upon future global sales. As part of the agreement, Ichnos is manufacturing batches of ISB 880 to support early clinical studies to be sponsored by Almirall.
- ISB 880, a fully-human, high-affinity, monoclonal antibody blocking IL-1RAP signaling, has completed IND-enabling studies for patients with autoimmune diseases. The optimal antibody profile, the strong *in vitro* and *in vivo* data package, as well as toxicology, CMC, and clinical pharmacology plans enabled U.S. IND filing by Almirall, and initiation of a Phase 1 study is underway.
- Blockade of IL-1RAP simultaneously abrogates multiple disease drivers among the IL-1 family of proinflammatory cytokine receptors, including IL-1R, IL-33R, and IL-36R, differentiating ISB 880 from single cytokine blockade therapies. These cytokines have been implicated in numerous autoimmune conditions, opening opportunities for ISB 880 to be positioned across broad disease indications.
- To date, there is no IL-1RAP antagonist approved or under clinical development for autoimmune disease, positioning ISB 880 as a potential first-in-class therapeutic.
- Ichnos will retain rights for antibodies acting on the IL-1RAP pathway for oncology

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indications.

ISB 830 (TELAZORLIMAB, OX40 ANTAGONIST)

- The database for the ISB 830-204 Phase 2b clinical study in atopic dermatitis was locked in October 2021, and the final results were recently posted on [ClinicalTrials.gov](https://clinicaltrials.gov). This study, which was conducted in the U.S., Canada, Germany, Czech Republic, and Poland, had a randomized, controlled, multicenter design and assessed three doses and two dosing schedules of telazorlimab versus placebo in adults with moderate-to-severe atopic dermatitis (AD).
- Results from the double-blind portion of the study are summarized below:
  - + **Efficacy:** The primary endpoint of the EASI score, % change from baseline to Week 16, was achieved for the two highest doses of telazorlimab tested (300 mg and 600 mg q 2 weeks) versus placebo.
  - + **Safety:** Telazorlimab was well tolerated. The most commonly reported adverse events (>5%) were atopic dermatitis, nasopharyngitis, upper respiratory tract infection, and headache. One patient with pre-existing hypertension in the telazorlimab group died due to a presumed cardiovascular event during the treatment period. The investigator considered the death to be unrelated to the study drug.
- Ichnos has clearance from the FDA to study telazorlimab in seropositive autoimmune diseases (Rheumatoid Arthritis, Systemic Lupus Erythematosus, Sjogren's Syndrome, Multiple Sclerosis, Type I Diabetes Mellitus, Myasthenia Gravis), and is actively seeking a partner to further develop the drug in atopic dermatitis and other indications.