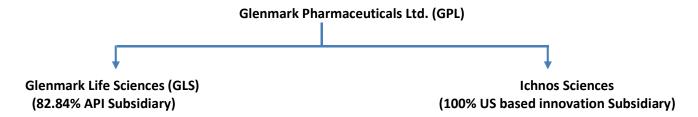


# Management Discussion & Analysis for the Third Quarter of FY 2021-22

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)

	Third quarter ended December 31			Nine months ended December 31			
	FY 2021-22	FY 2020-21	Growth (%)	FY 2021-22	FY 2020-21	Growth (%)	
India	10,069	8,821	14.2%	32,009	27,127	18.0%	
North America	7,567	7,804	-3.0%	22,988	22,752	1.0%	
Europe	3,807	3,133	21.5%	10,250	9,053	13.2%	
Rest of the World (ROW)	4,178	3,360	24.3%	13,390	9,286	44.2%	
Latin America	1,170	1,286	-9.0%	2,804	2,927	-4.2%	
API	3,032	3,201	-5.3%	9,426	8,762	7.6%	
Total	29,823	27,605	8.0%	90,865	79,908	13.7%	
Other Revenue	1,911	263	627.9%	1,992	932	113.8%	
Consolidated Revenue	31,734	27,868	13.9%	92,858	80,840	14.9%	

Average conversion rate in 9M FY 2021-22 considered as INR 74.15/USD 1.00 Average conversion rate in 9MFY 2020-21 considered as INR 74.40/USD 1.00 USD figures are only indicative



#### Review of Operations for the quarter ended on December 31, 2021

For the third quarter of FY 2021-22, Glenmark's consolidated revenue was at Rs. 31,734 Mn. (USD 424 Mn.) as against Rs. 27,868 Mn. (USD 378 Mn.) recording an increase of 13.9 % YoY.

For the nine months ended December 31, 2021, Glenmark's consolidated revenue was at Rs. 92,858 Mn. (USD 1,252 Mn.) as against Rs. 80,840 Mn. (USD 1,087 Mn.) recording an increase of 14.9% YoY.

#### **Key Highlights**

Glenmark was listed in the prestigious Dow Jones Sustainability Index (DJSI) for the fourth consecutive year. The company is among only 15 companies from India to be listed on the DJSI Emerging Markets Index this year. The DJSI is one of the world's most respected and widely accepted sustainability benchmarks globally, and the company's inclusion is a validation of its commitment to sustainability and ESG principles and reiterates its consistent performance across all sustainability indicators.

A detailed ESG profile of the company is available under the investor section on our website.

Glenmark was selected for the Production Linked Incentive (PLI) scheme aimed at improving India's manufacturing capabilities and enhancing exports. Glenmark is one of the 11 companies under group A and is well placed to meet the objectives and guidelines of the scheme thereby helping in the "Aatmanirbhar Bharat" strategy of the government.

#### **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 in 3QFY22 was at Rs. 10,069 Mn as against Rs. 8,821 Mn. in the previous corresponding quarter, recording growth of 14.2 % YoY and 3.9% QoQ. As per Oct-Dec '21 IQVIA data, the non-COVID base portfolio grew 15.5% as compared to the non-COVID IPM growth of 11.7% during the quarter.

The India business continues to outperform the industry growth and has grown consistently over the past several years. Glenmark is the one of the fastest growing companies (among top 20 companies) on MAT Dec 2021 basis. As per IQVIA MAT Dec '21 data, Glenmark's India business recorded growth of 23.9% compared to IPM growth of 16.9%. The company increased its market ranking to 13<sup>th</sup> from 14<sup>th</sup> with market share of 2.48% as compared to 2.34% last year.

As per IQVIA MAT Dec '21, Glenmark's India business further strengthened its position in its core therapy area in respiratory with market share increasing to 5.36% as compared to 5.11% in Q3 last year. Similarly, market share in cardiology has increased to 4.86% as compared to 4.74% last year.



Glenmark is now ranked 5<sup>th</sup> in cardiology from 6<sup>th</sup> earlier and has retained its rankings of 2<sup>nd</sup> in dermatology and 4<sup>th</sup> in respiratory markets in India during the quarter. The company launched 8 new products during the quarter. Amongst key launches during the quarter, the company launched the first triple combination of Remogliflozin, Vildagliptin and Metformin in diabetes segment under the brand name Remo MV/Remozen MV. In addition, the company also launched the only Ultra Laba and ICS combination in India with once a day dosing schedule in Vilanaterol & Fluticasone Capsules for the treatment of COPD under the brand name Vilor F and Midostaurin, Pazopanib and Darbepoetin in Oncology segment.

The India formulation business has achieved several important milestones during the current financial year. As per IQVIA MAT Dec '21, Fabiflu® was the third largest brand across all brands in India during the period. Telma became the second brand of the company to achieve sales of Rs 300 cr as per IQVIA. Ascoril D Plus became the 10<sup>th</sup> brand of Glenmark to enter the IPM 300 brand league.

Remogliflozin continues to do well in India. Glenmark is the first company in the world to launch Remogliflozin and has launched multiple brand extensions, including combinations to leverage its positioning around the product. This strategy is showing results with total Remogliflozin sales, including brand extensions and combinations growing in double digits during the quarter.

The company recently received manufacturing and marketing approval for Nitric Oxide Nasal Spray in India as a part of the accelerated approval process for treatment of adult patients with Covid 19 who have high risk of progression of the disease. Phase III trials in India demonstrated reduction in viral load of 94% in 24 hours and 99% in 48 hours and the product was safe and well tolerated in Covid 19 patients. The product has been launched in India under Glenmark brand FabiSpray® Glenmark has an exclusive long-term agreement with Canadian biotech SaNOtize to commercialize FabiSpray® for COVID-19 treatment in Indian and certain other Asian markets.

#### India – Glenmark Consumer Care Business

GCC business recorded revenue of Rs. 358 million in the third quarter. New launches like Candid Cream and La Shield delivered strong robust growth during the quarter. Secondary sales in Candid Cream grew 32% YoY while La Shield recorded secondary sales growth of 89% YoY. Candid Powder faced headwinds during the quarter due to COVID impact and base effect of last year. The brand continued to maintain its dominant market leadership status with a market share of 63.4% in the current financial year. As mentioned earlier, Candid Powder is the first brand in the Consumer Care Business to enter the "Rs. 100 Cr" club.

#### **North America**

North America registered revenue from the sale of finished dosage formulations of Rs. 7,567 Mn (USD 101 Mn) for the quarter ended December 31, 2021 as against revenue of Rs.7,804 Mn (USD 106 Mn) for the previous corresponding quarter, recording de-growth of (3.0)% YoY and growth of 1% QoQ.

In the third quarter of fiscal year 2021-22, Glenmark launched Abiraterone Acetate Tablets 250 mg and Clindamycin and Benzoyl Peroxide Gel. The Company filed 13 ANDA applications with the U.S. FDA including 4 filings from Monroe in 9MFY22 and is on track to file 18-20 ANDAs in FY22 including 4-5 filings from Monroe during the current financial year.



In January '22, the company received USFDA approval for its first NDA product Ryaltris, highlighting the company's commitment to innovation to create breakthrough therapies and promising treatments for the benefit of patients. Ryaltris will be marketed in the US through our partner Hikma.

Glenmark's marketing portfolio through December 31, 2021 consists of 172 generic products authorized for distribution in the U.S. market. The Company currently has 47 applications pending in various stages of the approval process with the US FDA, of which 20 are Paragraph IV applications.

#### **Europe**

Glenmark Europe's operations revenue for the third quarter of FY 2021-22 was at Rs. 3,807 Mn(USD 51 Mn) as against Rs. 3,133 Mn. (USD 43 Mn.) recording growth of 21.5 % YoY and 13.3% QoQ.

The company witnessed healthy growth in both its key markets of Western Europe and Central Eastern Europe during the quarter. Despite continued Covid restrictions in some countries like Germany, overall growth in Western Europe was strong, led by double digit growth in markets like UK and Netherlands. In the Central Eastern European region, growth momentum continued across all key markets. The European region has signed nine contracts for in-licensing products in the current financial year. Amongst the key launches, the company launched two products in Germany and one product each in United Kingdom and Spain during the quarter.

In-line with our global focus on the respiratory segment, the company further launched Tiotropium Dry Powder Inhaler, the bioequivalent version of Spiriva Handihaler in Germany, Denmark and Sweden during the quarter making a total of seven countries in Europe where the company has launched the product. Further, the company launched Ryaltris™ in UK, Poland and in the Czech Republic in the quarter and the response has been encouraging. The company has detailed plans to launch both products in multiple other markets in Europe, both with our front end and with partners in the coming quarters.

#### RCIS, Asia and MEA Region (RoW)

For the third quarter of FY 2021-22, revenue from RoW was Rs. 4,178 Mn (USD 56 Mn) as against Rs. 3,360 Mn. (USD 46 Mn) for the previous corresponding quarter, recording growth of 24.3% YoY.

The company witnessed healthy growth in base business in the region across all its key geographical segments.

Growth momentum continues in Russia and across CIS markets. Secondary sales grew 12% YoY and 66% YoY in value terms in Russia and Ukraine respectively. As per IQVIA, Russia segment grew 20.8% in value terms as compared to retail market growth of 10.7% in Q3. The overall response to Ryaltris and Ryaltris Mono has been very encouraging in the market.

Secondary sales in Asia grew 22% YoY led by positive momentum in key markets like Vietnam, Malaysia, and Philippines. Glenmark's first global specialty brand Ryaltris was launched in Philippines during the quarter. The company plans to commercialize FabiSpray® in the region from Q4 FY22 under the brand name VirX®.



The Middle East and the Africa region recorded strong growth with secondary sales growing by 24% YoY during the current financial year. The growth across all the major MEA markets including Kenya and South Africa was positive.

#### **Latin America**

Glenmark's revenue from its Latin American & Caribbean operations was at Rs. 1,170 Mn (USD 16 Mn) for the third quarter of FY 2021-22 as against Rs. 1,286 Mn. (USD 17 Mn.), recording revenue decline of (9.0)% YoY. The business has been impacted by Brazil where the market remained challenging for the company due to the pandemic. Company recorded positive growth momentum in some markets including Peru, Ecuador and the Caribbean during the quarter.

#### **GPL Specialty/Innovative R&D Pipeline**

#### Ryaltris™

In Jan 2022, Ryaltris™ (olopatadine hydrochloride and mometasone furoate) Nasal Spray, received FDA approval in the United States for the treatment of symptoms of Seasonal Allergic Rhinitis in adults and patients 12 years of age and older. During the third quarter. Glenmark also received approvals in Myanmar and Kenya in Q3 FY22. The company is awaiting regulatory approvals for its filings in Canada, Brazil, Malaysia, and several other emerging markets.

Ryaltris sales continue to grow in Australia, the Czech Republic, Poland, Russia, South Africa, Ukraine, the United Kingdom, and Uzbekistan. Glenmark initiated the commercial launch in Philippines, in Q3 FY21-22 and plan to launch in Peru and Ecuador in Q4. Menarini, Glenmark's partner in select EU markets, is targeting launch in key markets in Q4 FY22.

Glenmark is working with its partner in South Korea, Yuhan Corporation, to enable commercial launch shortly. Glenmark's partner in Mainland China, Grand Pharmaceutical (China) Co. Ltd., received CDE approval for the Ryaltris IND in October 2021 and plans to initiate a Phase 3 study in the fourth quarter. Glenmark's partner in Australia, Seqirus Pty Ltd. expects TGA approval for pediatric (6-11 yrs) indication expansion to be granted in the next few quarters

#### **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 U.S. under the brand name Xolair®.

#### **GRC 39815 (RORyt inhibitor)**

GRC 39815 (RORyt antagonist) is the company's respiratory pipeline asset being developed as an inhaled therapy for treatment of mild to moderate COPD. It is currently under Phase 1 clinical development with a single ascending dose study in the US.



#### **GRC 17536**

GRC 17536 (TRPA1 antagonist) is the company's pain pipeline asset being developed as an orally administered treatment for pain in patients with painful diabetic peripheral neuropathy. The Phase 2b study was initiated in Q2 FY22 and is currently ongoing in India with 128 patients randomized till date. GLP toxicology studies for metabolite qualification were completed in Q3 FY22.

#### **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. Pre-clinical in-vitro and in-vivo profiling was completed in Q1 FY22 and Pre-clinical DMPK and non-GLP Toxicology studies were completed and IND enabling studies were initiated in Q3 FY22. Phase I IND submission is planned in Q4 FY22.

#### **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).

For the third quarter of the financial year, revenues from operations including captive sales were Rs. 5,225 Mn as against Rs. 5,002 Mn, growing at 4.5% YoY. During the quarter, revenues from the regulated markets witnessed healthy growth whereas revenues from the emerging markets were lower due to high base of COVID products sales last year. The EBITDA margins stood at 28.6% for Q3 FY22.

External sales for Glenmark Life Sciences were at Rs. 3,032 Mn as against Rs. 3,201 Mn in Q3 FY21, recording decline of (5.3)% YoY and 7.6% growth QoQ. The growth was impacted due to higher base of COVID products in the previous year.

The company is in the process of executing brownfield and greenfield capacity expansion projects to support strategic growth levers.

For further updates on the organization, please log on to <a href="www.glenmarklifesciences.com">www.glenmarklifesciences.com</a>.

#### **ICHNOS Sciences**

For the third quarter of the financial year, Glenmark invested Rs. 1,520 Mn (USD 20.5 Mn) as compared to Rs. 1,713 Mn (USD 23.0 Mn) invested in the corresponding quarter of the previous financial year. For the first nine months of the current financial year, Glenmark has invested Rs. 4,987 Mn (USD 67.5 Mn) as compared to Rs. 5,693 Mn (USD 76.3 Mn) invested in the corresponding periodof the previous financial year.

During the quarter, Ichnos entered into an exclusive licensing agreement with Almirall SA for the IL-1RAP antagonist ISB 880. Under the agreement, Almirall is granted global rights to develop and commercialize this monoclonal antibody for autoimmune diseases. Ichnos retains the rights for



antibodies acting on the IL-1RAP for oncology indications. Ichnos received an upfront payment of Eur 20.8mn and will receive additional development and commercial milestone payments and tiered royalties based upon future global sales.

For further updates on the pipeline and the organization, please log on to <a href="www.ichnossciences.com">www.ichnossciences.com</a>. The pipeline update for the third quarter of this financial year is published on this site.

#### **Key objectives for FY22**

- Revenue growth of 10-15% during the year
- Sustain EBITDA margin performance at similar levels of FY21
- Reduce debt by at least Rs. 16 Bn through a combination of free cash generation and IPO proceeds during the year
- Post FY22, strategic priority to enhance free cash generation for further debt reduction; prioritizing over R&D investments and capital expenditure
- Close 1-2 out-licensing agreements at Ichnos



#### Disclaimer

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# ICHNOS SCIENCES INC.

#### FEBRUARY 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.



The proprietary BEAT® technology platform¹ 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.

 $<sup>^{\</sup>rm 1}$  Bispecific Engagement by Antibodies based on the TCR

ichnos

#### 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.

MOLECULE MECHANISM/CLASS	PHASE/STATUS	LEAD INDICATION
ISB 1342 CD38 x CD3 BEAT® 1.0 bispecific antibody	Phase 1	Relapsed/Refractory Multiple Myeloma
ISB 1442 CD38 x CD47 BEAT® 2.0 bispecific antibody	IND-Enabling Studies	Relapsed/Refractory Multiple Myeloma and Select Hematologic Malignancies
ISB 2001 TREAT™ trispecific antibody	Discovery	Hematologic Malignancies
ISB 2004 BEAT® 2.0 bispecific antibody	Discovery	Hematologic Malignancies/ Solid Tumors
ISB 2005 TREAT™ trispecific antibody	Discovery	Hematologic Malignancies

#### 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 in the end of 2021 to enhance enrollment. New locations in the U.S. were added and 11 sites have opened for enrollment in France and are now recruiting subjects.
  - + Clinical proof of concept in the ongoing study is anticipated in the middle 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).

# ichnos

- + 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 <u>2021 ASCO Annual Meeting</u> 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-SIRPα 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.
- IND-enabling studies are proceeding, and IND filing is planned for second quarter of calendar year 2022. A Phase 1/2 first-in-human dose-finding study of ISB 1442 in relapsed/refractory multiple myeloma and other select hematologic malignancies is currently planned to start in the middle of 2022.
- 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 <u>link</u>, 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 models
  - + Low on-target off-tumor binding with ISB 1442 compared to anti-CD47 mAb (5F9), resulting in lower red blood cell depletion and potentially a better therapeutic index than anti-CD47 bivalent monoclonal antibodies
- The first bulk drug substance batches to support IND filing and early clinical studies were manufactured at the Ichnos site in La Chaux-de-Fonds, Switzerland in 2021.

#### ISB 2001 TREAT™ TRISPECIFIC ANTIBODY

- Based on BEAT<sup>®</sup> 2.0 technology, ISB 2001 trispecific antibody (TREAT<sup>™</sup>) represents a first-in-class potential treatment for hematologic malignancies and is designed to extend therapeutic durability.
- Identification and amino acid sequence lock of the top two candidates was achieved in 2021. Preclinical evaluation of in vivo efficacy, PK/PD correlation, additional biophysical properties description, late pharmacology studies and other attribute-defining studies are ongoing this quarter, and the results will inform the selection of the drug product candidate in the first half of calendar year 2022.
- Process development is ongoing at the Ichnos site in La Chaux-de-Fonds, Switzerland.

#### AUTOIMMUNE DISEASES

Ichnos has two monoclonal antibody drug product candidates addressing autoimmune diseases in the pipeline. The first, ISB 880, an anti-IL-1RAP antagonist, was licensed to Almirall, S.A. in December 2021, and 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 out-licensing discussions. Both compounds have potential across a range of autoimmune diseases and are being out-licensed to enable a greater focus on oncology.

#### ASSETS IN AUTOIMMUNE DISEASE

MOLECULE MECHANISM/CLASS	POTENTIAL INDICATIONS	PHASE	STATUS	
ISB 880 IL-1RAP Antagonist Monoclonal Antibody	Autoimmune Diseases	IND- enabling studies completed	Licensed to Almirall S.A. in December 2021. Almirall's U.S. IND filing is planned for first half of calendar year 2022.	
ISB 830 Telazorlimab OX40 Antagonist Antibody	Atopic Dermatitis	Phase 2b	Successfully completed a Phase 2b study in atopic dermatitis. Outlicensing discussions ongoing.	
	Other autoimmune diseases, including Rheumatoid Arthritis	U.S. IND for RA 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 and the deal also includes development and commercial milestone payments and tiered royalties based upon future global sales.
- 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 will enable U.S. IND filing by Almirall in the first half of calendar year 2022.
- 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 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. 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 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. Numerical improvements were also seen for the two higher dose arms of telazorlimab compared to placebo in the secondary endpoints of EASI-75 and Investigator Global Assessment, but most of the differences were not statistically significant.

	Part 1				Part 2	
	TELAZORLIMAB 300 MG Q2W (n=76*)	TELAZORLIMAB 300 MG Q4W (n=78*)	TELAZORLIMAB 75 MG Q4W (n=77*)	PLACEBO (n=80*)	TELAZORLIMAB 600 MG Q2W (n=75*)	PLACEBO (n=74*)
EASI Score % Change from Baseline to Week 16 Mean (SD)	-57.59 (36.20)	-56.73 (32.54)	-38.10 (39.69)	-42.14 (38.19)	-59.74 (27.12)	-43.25 (41.24)
P-value	0.008	0.061	0.691	n/a	0.008	n/a

Q2W, every 2 weeks; Q4W, every 4 weeks; n/a, not applicable

- + **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.
- In addition to data from the 16-week primary analysis period, preliminary results from the open-label extension and follow-up period of this study, which was ongoing at the time, were presented at the 2021 Society for Investigative Dermatology Virtual Meeting and are accessible <a href="here">here</a>. Of note:

<sup>\*</sup>Includes subjects who were randomized and dosed. Subjects who received rescue medication for atopic dermatitis during the study are considered non-responders in the efficacy analyses.

- + Clinical efficacy continued to improve after Week 16, with maximal impact achieved several weeks later
- + Reduction in AD disease activity was maintained after discontinuation of telazorlimab, through three months of follow-up
- A U.S. IND to conduct studies of telazorlimab in autoimmune diseases, including Rheumatoid Arthritis (RA), is active.
- · Licensing discussions are ongoing.