

May 23, 2025

To,  
Dy. General Manager  
Department of Corporate Services,  
BSE Ltd.,  
P. J. Towers, Dalal Street,  
Fort, Mumbai – 400 001

To,  
The Manager – Listing,  
National Stock Exchange of India Ltd.,  
Plot No. C/1, G Block,  
Bandra Kurla Complex,  
Bandra (E), Mumbai – 400 051

Ref: Scrip Code: 532296

Ref: Scrip Name: GLENMARK

Dear Sirs,

**Sub: Press Release and Management Discussion & Analysis**

Pursuant to regulation 30 of the SEBI (Listing Obligations and Disclosure Requirements), 2015, we are enclosing herewith the Press Release and Management Discussion & Analysis of the Company for the Fourth Quarter and year ended March 31, 2025.

You are requested to take the same on record.

Thanking You.

Yours faithfully,  
**For Glenmark Pharmaceuticals Limited**

**Harish Kuber**  
**Company Secretary & Compliance Officer**

Encl: As above

**Glenmark Pharmaceuticals Limited**

Glenmark House, B D Sawant Marg, Andheri (E), Mumbai 400 099

T: 91 22 4018 9999 F: 91 22 4018 9988 CIN: L24299MH1977PLC019982 W: [www.glenmarkpharma.com](http://www.glenmarkpharma.com)

Registered office: B/2, Mahalaxmi Chambers, 22 Bhulabhai Desai Road, Mumbai 400 026 E: [complianceofficer@glenmarkpharma.com](mailto:complianceofficer@glenmarkpharma.com)

## **Glenmark Pharma Reports Q4 & FY25 Financial results**

### **Highlights for FY2025**

- *India business grew by 31.9% to Rs. 44,845 Mn*
- *Europe business grew by 17.6% to Rs. 28,463 Mn*
- *RoW business grew by 1.7% to Rs. 28,138 Mn*
- *EBITDA of Rs. 23,510 Mn with EBITDA margin of 17.6%*
- *Adjusted Profit After Tax (PAT)<sup>#</sup> of Rs. 13,894 Mn with Adjusted PAT margin<sup>#</sup> of 10.4%*

**Mumbai, India, May 23, 2025:** Glenmark Pharmaceuticals Ltd. (Glenmark), a research-led, global pharmaceutical company, today announced its financial results for Q4FY25 ended March 31, 2025.

### **Q4FY25 Results:**

- For the fourth quarter of FY 2024-25, Glenmark's consolidated revenue was at Rs. 32,562 Mn as against Rs. 30,630 Mn recording an increase of 6.3% YoY.
- EBITDA was Rs. 5,607 Mn in the quarter ended March 31, 2025, as compared to Rs. 5,043 Mn in the previous corresponding quarter, registering growth of 11.2%. EBITDA margin for the quarter was 17.2%.
- Adjusted Profit After Tax (PAT)<sup>#</sup> for the quarter ended March 31, 2025 was at Rs. 3,466 Mn with adjusted PAT margin<sup>#</sup> of 10.6%.

### **FY25 Results:**

- For the year ended March 31, 2025, Glenmark's consolidated revenue was at Rs. 1,33,217 Mn as against Rs. 1,18,131 Mn, recording an increase of 12.8% over the previous corresponding period.
- EBITDA for the fiscal year ended March 31, 2025 stood at Rs. 23,510 Mn as against Rs. 11,953 Mn in the previous corresponding period. EBITDA margin for FY 2024-25 was at 17.6%.
- Adjusted Profit After Tax (PAT)<sup>#</sup> for the year ended March 31, 2025 was at Rs. 13,894 Mn, with adjusted PAT margin<sup>#</sup> of 10.4%.

**Commenting on the results, Glenn Saldanha, Chairman & Managing Director, Glenmark Pharmaceuticals Ltd. said,** "Our performance reflects the underlying resilience of our business, the strength of our diversified portfolio, and the focused execution of our strategic priorities. The Europe business has shown strong growth, and our branded businesses have delivered sustained results, supported by market expansion and a sharp therapeutic focus. As we move into FY26, we remain committed to building this momentum as we strengthen our global footprint.

We are also proud to share that our innovation-led pipeline continues to gain momentum, with Ichnos Glenmark Innovation (IGI) receiving US FDA Fast Track designation for ISB 2001 — a significant milestone in our journey towards advancing cutting-edge biologics for cancer care. This recognition marks a critical step forward in our aspiration to bring transformative therapies to patients and reinforces our commitment to being a science-led, future-ready organization."

## **India**

Sales from the formulation business in India in Q4FY2025 was at Rs. 9,430 Mn as against Rs. 9,391 Mn in the previous corresponding quarter, recording growth of 0.4% YoY.

## **North America**

North America registered revenue from the sales of finished dosage formulations of Rs. 7,146 Mn for the quarter ended Mar 31, 2025 as against revenue of Rs. 7,557 Mn for the previous corresponding quarter, recording decline of 5.4% YoY.

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

For the fourth quarter of FY 2025, revenue from RoW was Rs. 7,898 Mn as against Rs. 7,528 Mn for the previous corresponding quarter, recording growth of 5% YoY.

## **Europe**

Glenmark Europe's operations revenue for the fourth quarter of FY 2025, that was at Rs. 7,335 Mn as against Rs. 6,118 Mn, and recording growth of 20% YoY.

*#Adjusted for the one-time exceptional items associated with generic Zetia® litigation along with associated legal costs and closure of manufacturing facility at La Chaux-de-Fonds, as reported in the Q4FY25 P&L statement*

## **About Glenmark Pharmaceuticals Limited**

Glenmark Pharmaceuticals Ltd. (BSE: 532296 | NSE: GLENMARK) is a research-led, global pharmaceutical company, having a presence across Branded, Generics, and OTC segments; with a focus on therapeutic areas of respiratory, dermatology and oncology. The company has 11 world-class manufacturing facilities spread across 4 continents, and operations in over 80 countries. In Vivo/Scrip 100 positions Glenmark amongst the Top 100 Companies Ranked by R&D and Pharmaceutical Sales, 2022; while Generics Bulletin/In Vivo places it in the Top 50 Generics and Biosimilars Companies Ranked by Sales, 2022. Glenmark's Green House Gas (GHG) emission reduction targets have been approved in 2023 by the Science Based Target initiative (SBTi), making it only the second pharmaceutical company in India to achieve this. The organization has impacted over 3 million lives over the last decade through its CSR interventions. For more information, visit [www.glenmarkpharma.com](http://www.glenmarkpharma.com). You can follow us on LinkedIn (Glenmark Pharmaceuticals) and Instagram ([glenmark\\_pharma](https://www.instagram.com/glenmark_pharma)).

## **For media queries, please contact:**

Swapnil Mishra | [corpcomm@glenmarkpharma.com](mailto:corpcomm@glenmarkpharma.com) | +91 9164107444

## Management Discussion & Analysis for the Fourth Quarter of FY 2024-25

### Revenue Figures for Glenmark Pharmaceuticals Ltd.

(In Rs. Million)

	For the fourth quarter ended March 31			For the twelve months ended March 31		
	FY 2024-25	FY 2023-24	Growth (%)	FY 2024-25	FY 2023-24	Growth (%)
<b>India</b>	9,430	9,391	0.4%	44,845	33,994	31.9%
<b>North America</b>	7,146	7,557	-5.4%	30,172	30,943	-2.5%
<b>Europe</b>	7,335	6,118	19.9%	28,463	24,205	17.6%
<b>Rest of the World<sup>1</sup></b>	7,898	7,528	4.9%	28,138	27,666	1.7%
<b>Total</b>	<b>31,809</b>	<b>30,594</b>	<b>4.0%</b>	<b>131,618</b>	<b>116,807</b>	<b>12.7%</b>
<b>Other Revenue</b>	753	36	2021.5%	1,599	1,324	20.8%
<b>Consolidated Revenue</b>	<b>32,562</b>	<b>30,630</b>	<b>6.3%</b>	<b>133,217</b>	<b>118,131</b>	<b>12.8%</b>

1. Russia + CIS (RCIS), Latin America (LATAM), Middle East and Africa (MEA), Asia-Pacific (APAC)

Average conversion rate in 12M FY 2024-25 considered as INR 84.54 / USD 1.00

Average conversion rate in 12M FY 2023-24 considered as INR 82.78 / USD 1.00

USD figures are only indicative

## Review of Operations for the Quarter ended March 31, 2025

For the fourth quarter of FY25, Glenmark's consolidated revenue from operations was at Rs. 32,562 Mn (USD 375.8 Mn) as against Rs. 30,630 Mn (USD 368.9 Mn) in the corresponding quarter last year, recording overall year-on-year (YoY) growth of 6.3%.

For the twelve months of FY25, Glenmark's consolidated revenue was Rs. 1,33,217 Mn (USD 1,575.8 Mn) as against Rs. 1,18,131 Mn (USD 1,427.1 Mn), recording a YoY growth of 12.8%.

## Key Highlights for the Fiscal Year 2025

- Glenmark assumed leadership position in its key therapeutic areas in India, ranking 2<sup>nd</sup> in Dermatology and 3<sup>rd</sup> in Cardiac segment respectively in the fourth quarter of FY25
- Glenmark's Europe business continued its strong performance, growing at 17.6% for FY25
- RYALTRIS® was launched in more than 10 markets in FY25 and is now commercialized in 45+ markets globally
- WINLEVI® received approval from the Medicines and Healthcare Products Regulatory Agency (MHRA) in the United Kingdom
- IGI presented first-time safety and efficacy data for 20 heavily pre-treated patients, from its Phase 1 (Part 1) study of ISB 2001 in an oral presentation at the 66th American Society of Hematology (ASH) Annual Meeting in San Diego, CA.

## FORMULATION BUSINESS

Glenmark's global formulation business is spread across Branded, Generics, and OTC segments in the therapy areas of Dermatology, Respiratory and Oncology, along with strong regional/country-specific presence in other therapeutic areas like Cardiac, Diabetes and Oral Contraceptives.

### INDIA

Sales from the formulation business in India for the fourth quarter of FY25 was at Rs. 9,430 Mn (USD 108.3 Mn) as against Rs. 9,391 Mn (USD 113.1 Mn) in the corresponding quarter last year, recording a growth of 0.4%. The India business contribution to consolidated revenue was 33.7% in FY25.

Reported sales in the India region during the fourth quarter was impacted mainly due to:

- Continued weak growth in the acute Respiratory market, mainly due to low seasonal pick-up
- A highly competitive Diabetes market, resulting in a ~10% decline in the fourth quarter
- Discontinuation of select non-core, low-margin brands in the hospitals & trade generics segments to improve overall business margins

Despite the lower reported growth, Glenmark continued to significantly outperform the IPM in terms of secondary sales as per IQVIA. Glenmark's India formulation business recorded a growth of 10.3% in Q4 FY25 and 12.0% as per MAT March 2025, compared to the overall market growth of 6.9% in Q4 FY25 and 7.7% in MAT March 2025. Glenmark continued to outperform the overall market in its key therapeutic areas like Dermatology and Cardiac therapeutic areas. Growth in the Respiratory area was mainly driven by the chronic portfolio, which grew by 20%+ in the fourth quarter.

	IPM	GLENMARK	IPM	GLENMARK
SUPERGROUP	VALUE GROWTH (JAN'25 - MAR'25)	VALUE GROWTH (JAN'25 - MAR'25)	VALUE GROWTH (MAT MAR'25)	VALUE GROWTH (MAT MAR'25)
CARDIAC	10.0	11.0	11.9	16.1
DERMATOLOGY	7.0	17.0	9.3	18.9
RESPIRATORY	3.3	7.8	3.2	3.5
DIABETES	6.9	-9.4	8.5	-4.3

Glenmark's India business is ranked 13<sup>th</sup> with a market share of 2.25% (IQVIA MAT March 2025). The Company has 10 brands in the IPM Top 300 Brands in the country as of IQVIA MAT March 2025. In terms of key therapeutic areas, Glenmark was ranked 2<sup>nd</sup> in Dermatology, 2<sup>nd</sup> in Respiratory and 3<sup>rd</sup> in the Cardiac segment as per IQVIA Q4 FY25.

	GLENMARK	
SUPERGROUP	MARKET SHARE (%) MAT MAR'24	MARKET SHARE (%) MAT MAR'25
CARDIAC	5.7	5.9
DERMATOLOGY	7.5	8.2
RESPIRATORY	5.8	5.8
DIABETES	1.4	1.2

## EMPAGLIFLOZIN

- In March 2025, Glenmark launched Empagliflozin, a widely recognized SGLT2 inhibitor, in India.
- The drug has been introduced under the brand name GLEMPA™ (Empagliflozin 10/25 mg), along with its fixed-dose combinations (FDCs): GLEMPA-L™ (Empagliflozin 10/25 mg + Linagliptin 5 mg)

and GLEMPA-M™ (Empagliflozin 12.5 mg + Metformin 500/1000 mg).

#### **LIRAFIT™**

- The Company was the first to launch the biosimilar of Liraglutide under the brand name LIRAFIT™ in India. LIRAFIT™ has seen strong traction in the GLP-1 market in India post launch.
- The Company also plans to launch other GLP-1 agonists soon.

#### **JABRYUS® (PARTNERED WITH PFIZER)**

- In January 2024, Glenmark launched JABRYUS® (Abrocitinib), a first of its kind oral advanced systemic treatment for the treatment of moderate-to-severe atopic dermatitis (AD) in India in partnership with Pfizer.
- JABRYUS® has been well received by dermatologists as a novel treatment for moderate-to-severe AD, with improved efficacy and oral convenience to patients.

#### **TISLELIZUMAB AND ZANUBRUTINIB (PARTNERED WITH BEIGENE)**

- Glenmark and BeiGene entered into an agreement for marketing and distribution of Tislelizumab and Zanubrutinib in India in May 2024.
- Under this strategic collaboration, Glenmark will be responsible for locally required development, registration and distribution providing access to BeiGene's innovative oncology medicines for cancer patients across India.
- These two products will be launched in Q1 FY26.

#### **INDIA – GLENMARK CONSUMER CARE (GCC)**

Primary sales for GCC in Q4 FY25 were Rs. 852 Mn with a YoY growth of 23.5%. The Company's flagship brand Candid Powder™ delivered revenue growth of 15.2% for Q4 FY25. The Scalpe™ portfolio delivered a robust revenue growth of 73% YoY. The key variant, Scalpe Plus grew by ~40%, while Scalpe PRO registered 147% growth. La Shield™ portfolio delivered growth of 6.3%.

#### **NORTH AMERICA**

The North America business recorded revenues of Rs. 7,146 Mn (USD 82.4 Mn) for the fourth quarter of FY25 as against revenue of Rs. 7,557 Mn (USD 91.0 Mn) for the fourth quarter of FY24. This translates into a YoY decline of 5.4%. For FY25, the North America business contribution was 22.6%.

The US business continued to remain challenging due to lack of meaningful launches during the quarter. However, the Company expects an uptick in the business from FY26 onwards on the back of potential launches in the respiratory and injectable segments. Glenmark expects to launch some of its respiratory

products from H1 FY26 onwards. The Company also continues to augment its commercial portfolio through partnered product launches, which will help increase business growth in the near term.

In the fiscal year 2025, Glenmark was granted approval of 8 Abbreviated New Drug Applications (ANDA), comprised of 5 final approvals and 3 Prior Approval Supplement approvals. Glenmark completed the successful launches of 13 new products during fiscal year 2025, consisting of a mix of immediate-release oral solids, a semi-solid ointment, several injectables and an oral contraceptive. The Company filed a total of 4 ANDA applications with the U.S. FDA throughout the fiscal year.

In the fourth quarter of fiscal year 2025, Glenmark launched 7 products: Phytonadione Injectable Emulsion USP, 10 mg/mL, Clindamycin Phosphate Foam, 1%, Latanoprost Ophthalmic Solution USP, 0.005%, Epinephrine Injection USP, 10 mg/10 mL (1 mg/mL) – 10 mL Vials, Acetylcysteine Injection, 6 g/30 mL (200 mg/mL), Polyethylene Glycol 3350, Powder for Solution, Osmotic Laxative [OTC], and Vancomycin Hydrochloride for Injection USP.

Glenmark has a large commercial portfolio of injectable products for the US market. The Company has also leveraged its strong development capabilities in the Respiratory area to build a portfolio for the US market. The Company has filed two ANDAs for generic nasal sprays and is awaiting approval for the same. In addition, the Company filed the ANDA for gFlovent® 44mcg pMDI in May 2024. Glenmark is also working on filing the ANDA for the other two strengths of gFlovent®, as well as other respiratory products currently in the pipeline.

Glenmark's marketing portfolio through March 31, 2025, consists of 206 generic products authorized for distribution in the U.S. market. The Company currently has 51 applications pending in various stages of the approval process with the US FDA, of which 23 are Paragraph IV applications.

Note: All brand names and trademarks are the property of their respective owners. IQVIA National Sales Perspectives: Retail and Non-Retail, February 2025

In February 2025, Glenmark agreed to enter into a settlement with three plaintiffs, Humana, Centene and Kaiser, for a total of USD 7 Mn. This settlement was in respect of the ongoing litigation related to Glenmark's generic Zetia® launch. These plaintiffs had opted out of the settlement signed by Glenmark in 2023 with the three main plaintiff groups. The recent settlement made it clear that Glenmark denies each and every one of the allegations against it and the settlement is not based on Glenmark having conceded or admitted any liability or illegality.

## **EUROPE**

Glenmark Europe operations' revenue for the fourth quarter of FY25 was Rs. 7,335 Mn (USD 84.8 Mn) as against Rs. 6,118 Mn (USD 73.7 Mn) recording a growth of 19.9%. Europe business contributed 21.4% to the consolidated revenues in FY25.



Glenmark's Europe business continued its strong growth on the back of its branded business across all key markets in the region. The CEE region witnessed double-digit growth across all key markets on the back of a strong uptick in key products. The Western European markets also recorded double-digit growth for Glenmark. The branded Respiratory portfolio in Western European business sustained its growth momentum. RYALTRIS® continued to gain market share across all countries wherein the product was launched. The Company continues to focus on sustaining the increasing contribution from the branded markets / portfolio in Europe, mainly in the Respiratory and Dermatology therapeutic areas. The Company recently announced that it had received approval from the Medicines and Healthcare Products Regulatory Agency (MHRA) to market WINLEVI® in the United Kingdom. The Company is planning to launch WINLEVI® in the UK in FY26.

#### **ROW REGION (RCIS, LATAM, MEA & APAC)**

For the fourth quarter of FY25, revenue from the ROW region was Rs. 7,898 Mn (USD 91.5 Mn) as against Rs. 7,528 Mn (USD 90.7 Mn) for the corresponding quarter last year, recording a growth of 4.9%. The reported growth for the ROW region during the quarter continued to be impacted due to adverse currency movements in key markets. For FY25, the ROW business contribution was at 21.1%.

As per IQVIA MAT March 2025 data, Glenmark's Russia business recorded secondary sales growth of 10.2%. RYALTRIS® sustained its momentum and gained further market share during the quarter. In the Dermatology segment Glenmark demonstrated growth of 19.3% in value vs overall retail market growth of 16.6% in value as per IQVIA MAT March 2025. Amongst the Dermatology companies in Russia, Glenmark ranks 9<sup>th</sup> as per MAT March 2025. Amongst the companies present in the Expectorants market in Russia, Glenmark continues to be ranked 2<sup>nd</sup> as per MAT March 2025.

Glenmark's LATAM business recorded strong double-digit growth on the back of key launches in the Respiratory portfolio. The first generic of Salmeterol + Fluticasone MDI launched by Glenmark in the Brazilian market in Q1 FY25 continues to gain market share. Glenmark continues to be ranked amongst the top 5 companies in the Respiratory and Dermatology therapeutic areas in the Mexican Pharma market.

In the Middle East and Africa region, the Company continued to achieve secondary sales growth in key markets. Glenmark ranks 2<sup>nd</sup> in the overall pharmaceutical market in Kenya. RYALTRIS® continues to be the leading nasal spray for Allergic Rhinitis in South Africa and has seen strong pick-up post launch in key markets in the region.

In the Asia region, key markets such as Malaysia and the Philippines recorded double-digit secondary sales growth during the quarter and continued to grow faster than the market as per IQVIA MAT March 2025 data. RYALTRIS® continued to drive the significant outperformance in the Australian market. New product launches in Dermatology and Respiratory are expected to contribute to growth in the upcoming quarters.

## CREATING GLOBAL BRANDS

### **RYALTRIS®**

- As of March 2025, marketing applications for RYALTRIS® have been submitted to more than 90 countries across the world and the product has been commercialized in 45+ markets. Further, it is expected to be launched in 10-12 additional markets over the next few quarters
- As per IQVIA February 2025 data across markets, RYALTRIS® has seen robust performance in terms of both value and unit market shares\*. The product has achieved high double-digit market share in Australia, the Czech Republic, South Africa, Italy, Poland and other European markets. Further, RYALTRIS® continues to witness a strong uptake in markets where the product was recently launched across Europe and ROW regions.
- Menarini, Glenmark's partner in the EU, has witnessed a steady increase in market share across all its licensed markets.
- Yuhan Corporation, Glenmark's partner in the South Korean market, continued to perform well and enjoy double-digit market share as per IQVIA February 2025.
- Glenmark's partner in Mainland China, Grand Pharmaceutical (China) Co. Ltd., expects to receive the approval in FY26.

\*Market share: Top 10 products within "R1A1 – Nasal Corticosteroids without Anti-Infectives" category as per IQVIA + RYALTRIS® as of February 2025

### **ENVAFOLIMAB**

- Glenmark has filed Envafolimab in ~15 markets in FY25; the first market launch is expected in FY26.
- The Company has received authorization from the regulatory authority in Kenya for supply of Envafolimab via early access program
- Glenmark also plans to initiate a global multi-center Phase 3 study in neo-adjuvant / adjuvant NSCLC in FY26

### **WINLEVI®**

- The Company recently announced that Glenmark had received approval from the Medicines and Healthcare Products Regulatory Agency (MHRA) to market WINLEVI® in the United Kingdom
- The Company is planning to launch WINLEVI® in the UK in FY26.

## **ICHNOS GLENMARK INNOVATION (IGI)**

IGI features a robust pipeline of three innovative Oncology molecules targeting Multiple Myeloma and solid tumors, of which ISB 2001 is in clinical development. Additionally, IGI has two autoimmune disease assets that have been out licensed to leading companies and are in clinical development:

- **ISB 880 / ALM27134 (IL-1RAP ANTAGONIST)**

- IGI entered an exclusive global licensing agreement for ISB 880 in autoimmune diseases with Almirall in December 2021. Within the terms of the agreement, Almirall assumed full cost and responsibility for the global development and commercialization of the compound. The deal includes development and commercial milestone payments, and tiered royalties based upon future global sales.
- Almirall initiated a Phase 1 study in 2022, to evaluate the safety, pharmacokinetics, pharmacodynamics and clinical activity of the licensed asset.

- **ISB 830 (TELAZORLIMAB, OX40 ANTAGONIST)**

- IGI entered an exclusive global licensing agreement for ISB 830 and its follow-on ISB 830-X8 with Astria Therapeutics in October 2023.
- In January 2025, Astria announced initiation of a Phase 1a clinical trial of STAR0310, a potential best-in-class OX40 antagonist for the treatment of Atopic Dermatitis.

## **MULTIPLE MYELOMA OVERVIEW**

- Multiple myeloma (MM) remains a devastating and often fatal disease, with no current cure available. Despite advancements in treatment, many patients continue to face poor outcomes, especially those with relapsed or refractory (r/r) disease.
- The market for Multiple Myeloma therapies is projected to grow from \$23.5 billion in 2023 to approximately \$33 billion by 2030. This growth is driven by an aging population and increasing incidence of MM, highlighting the urgent need for effective treatments.

## **ISB 2001 TREAT™ TRISPECIFIC ANTIBODY FOR ONCOLOGY AND IMMUNOLOGY**

- ISB 2001 represents a groundbreaking approach in the fight against multiple myeloma. It is a tri-specific T cell engager (TCE) that targets BCMA and CD38 on MM cells while engaging CD3 on T cells to harness the body's immune system against cancer. This dual targeting mechanism enhances tumor cell destruction and offers a new pathway to address the challenges faced in treating r/r MM. Due to its mechanism of action as a TCE, ISB 2001 can also potentially be a viable therapeutic option for various autoimmune indications.
- ISB 2001 is amongst the first tri-specific antibodies developed for use in MM and received Orphan Drug Designation from the FDA in July 2023.
- IGI completed enrollment of the Phase 1 dose escalation (Part-1) in March 2025 and initiated/dosed the first patient in the dose expansion (Part-2) in April 2025
- In May 2025, the US FDA granted fast-track designation to ISB 2001 as a treatment for patients with relapsed/refractory multiple myeloma. Specifically, the indication includes patients who

have received 3 or more prior lines of treatment including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody.

#### **ISB 2001 DATA PRESENTATION AT ASH2024**

IGI presented first-time data from its Phase 1 study of ISB 2001 in an oral presentation at the 66th American Society of Hematology (ASH) Annual Meeting in San Diego, CA. The oral presentation detailed out the results from the dose-escalation portion of the study. ISB 2001 demonstrated a favourable safety profile in patients with heavily pre-treated r/r MM and recorded a strong efficacy profile with an Overall Response rate (ORR) of 75% across twenty heavily pre-treated patients. The complete presentation is available on <https://www.iginnovate.com/>.

#### **UPDATE ON IGI MANUFACTURING FACILITY**

In March 2025, IGI announced its plans to cease all CMC development and clinical supplies manufacturing at its facility in La Chaux-de-Fonds, Switzerland. IGI is progressing its pipeline, and it is anticipated that higher quantities of finished product will be required for future clinical programs. IGI CMC development and manufacturing of ongoing and future clinical programs will be moved to a network of well-established global Contract Development and Manufacturing Organizations (CDMOs).

#### **ISB 2001 DATA PRESENTATION AT ASCO 2025**

IGI will present first-in-human, Phase 1 dose-escalation data from ISB 2001 in the Rapid Oral Abstract Session – a format reserved for high-impact clinical science with the potential to shape the standard of care – at the upcoming 2025 American Society of Clinical Oncology (ASCO) Annual Meeting.

For further updates on IGI, including the pipeline assets, please log on to <https://www.iginnovate.com/>

#### **Disclaimer:**

This document has been prepared by Glenmark Pharmaceuticals Ltd. The information, statements and analysis made in this document describing the Company's or its affiliates' objectives, projections and estimates are forward-looking statements. These statements are based on current expectations, forecasts and assumptions that are subject to risks and uncertainties which could cause actual outcomes and results to differ materially from these statements, depending upon economic conditions, government policies and other incidental factors. No representation or warranty, either expressed or implied, is provided in relation to this document. This document should not be regarded by recipients as a substitute for the exercise of their own judgment. The Company undertakes no obligation to update or revise any forward-looking statements whether because of new information, future events or otherwise.

#####

# May 2025 Update

## About Ichnos Glenmark Innovation (IGI)

IGI, a global fully integrated clinical-stage biotech company developing multispecifics™ in oncology, with the aim to accelerate new drug discovery in cancer treatment. IGI combines research and development proficiencies in novel biologics with those in new small molecules to continue developing cutting-edge therapy solutions that treat hematological malignancies and solid tumors. Harnessing the combined proficiency of over 100 scientists and a robust pipeline of novel molecules, IGI looks to leverage the capabilities of its centers of innovation spread across the USA, Switzerland and India to propel Innovation. For more information, visit [www.iginnovate.com](http://www.iginnovate.com).

Headquartered in New York City, IGI has research and manufacturing operations at two sites in Switzerland. As a fully integrated biotechnology company with approximately 125 employees, IGI has strong capabilities in research, antibody engineering, small molecule, CMC, and clinical development of biotechnologies.

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

LEADERSHIP TEAM			PREVIOUS EXPERIENCE	BY THE NUMBERS
 <b>Cyril Konto, M.D.</b> President and Chief Executive Officer	 <b>Lida Pacaud, M.D.</b> Chief Medical Officer	 <b>Mario Perro, Ph.D.</b> Head of Biologics Research	 	<b>100+</b> Years combined experience in biotech and pharmaceuticals
 <b>Roberto Giovannini, Ph.D.</b> Chief Process & Manufacturing Officer	 <b>Dean Thomas, LL.M.</b> General Counsel	 <b>Sebastien Chenuet, Ph.D.</b> Head of Business Development	 	<b>30+</b> Products developed or launched
 <b>Karishma Sipahimalani, Ph.D.</b> Head of Human Resources			 	
			 	
			 	<b>40+</b> Mergers, acquisitions, IPOs and other transactions

The proprietary BEAT® technology platform<sup>1</sup> is one of the bases for IGI's 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>1</sup>Bispecific Engagement by Antibodies based on the TCR

## Oncology Pipeline

IGI's multispecific antibody and small molecule immune modulator pipeline, consists of three assets. This includes ISB 2001 (BCMAxCD38xCD3), which received orphan drug and fast track designations by the U.S. Food and Drug Administration (FDA) and is currently in dose-expansion Phase 1 clinical study for relapsed/refractory multiple myeloma (TRIgnite-1). GRC 65327 (Cbl-b inhibitor small molecule) is awaiting regulatory approval for initiating clinical development in India for solid tumors. ISB 2301 (NK-Cell Engager) is in the discovery stage for application in solid tumors. ISB 1442 (CD38 biparatopic x CD47) development has been discontinued, and the asset is available for licensing.

Updates of note in the last quarter are outlined below:

- + ISB 2001 completed enrollment of the phase 1 escalation (part-1) in March and initiated/dosed the first patient in the expansion (part-2) in April 2025
- + ISB 2001 EU CTA has passed validation on 27 March 2025
- + ISB 2001 FDA Fast Track designation has been granted on 23 April 2025
- + Three posters were presented at AACR in April 2025:
  - o ISB 2001: Clinical validation of a quantitative systems pharmacology (QSP) model of ISB 2001 used for deriving first in human (FIH) dose and efficient phase 1 dose escalation design in relapsed refractory multiple myeloma (RRMM) patients ([Link](#))
  - o ISB 2001: Pharmacokinetics (PK) and pharmacodynamics (PD) of ISB 2001, a novel BCMAxCD38xCD3 trispecific antibody from the First-in-Human (FIH) Phase 1 study in relapsed/refractory multiple myeloma patients ([Link](#))
  - o GRC 65327: Discovery of GRC 65327: A Best-in-Class, Selective and potent Cbl-b E3 ligase inhibitor for the treatment of advanced solid cancers ([Link](#))
- + ISB 2001 clinical data (encore) was presented at COMy in May 2025
- + ISB 2001 clinical abstract has been accepted at multiple conferences in H1 2025 and new clinical data will be presented in June 2025 at [ASCO2025](#) in the Rapid Oral Abstract Session, followed by Poster Presentation at EHA2025 (encore) also in June 2025

## Oncology-Focused Pipeline to Drive Long-Term Value Growth

ASSET	DESCRIPTION	INDICATION	PRECLINICAL	PHASE 1	PHASE 2	PHASE 3	STATUS
<b>CLINICAL ASSETS</b>							
ISB 2001	BCMA x CD38 x CD3 TREAT™ trispecific T-Cell Engager	Multiple Myeloma					PHASE 1 ORPHAN DRUG
GRC 65327	Cbl-b Inhibitor <b>Small Molecule</b>	Solid Tumors					PRE-CLINICAL
<b>CANDIDATES</b>							
ISB 2301	IMMUNITE™ NK-Cell Engager	Solid Tumors					DISCOVERY

## Partnering-Ready Asset to Accelerate Short-Term Value Creation

ASSET	DESCRIPTION	INDICATION	PRECLINICAL	PHASE 1	PHASE 2	PHASE 3	STATUS
<b>CLINICAL ASSETS</b>							
ISB 1442	CD38 biparatopic x CD47 BEAT® <b>Myeloid-Cell Engager</b>	Multiple Myeloma					PHASE 1 ORPHAN DRUG

IGI is looking for asset-level and platform-level collaboration partners in development and research. For more information, visit <https://IGInnovate.com/contact/>.



# Overview of Oncology Candidates in Development

## ISB 2001 TREAT™ TRISPECIFIC ANTIBODY

- ISB 2001 is a first-in-class T cell-engaging antibody that targets BCMA and CD38 on multiple myeloma cells. It is a trispecific antibody based on IGI's proprietary BEAT® platform, allowing maximal flexibility and excellent manufacturability of full-length multispecific antibodies.
- ISB 2001 combines three proprietary Fab 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 multiple myeloma cells. Its Fc domain was fully silenced to suppress Fc effector functions.
- 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 antigens instead of one, ISB 2001 is expected to be more resistant to antigen escape associated with treatment of multiple myeloma patients.
- At the AACR Annual Meeting in 2024, an oral presentation showcased the results of ISB 2001 anti-myeloma activity ex-vivo in bone marrow aspirates from patients who have relapsed after CD38 and BCMA targeted therapies. ISB 2001 demonstrated superior cytotoxicity relative to teclistamab in the samples of patient relapsing from CD38 and BCMA targeted immunotherapies.
- The preclinical data package for ISB 2001 was in 2024 published in [Nature Cancer](#) and shows that:
  - + ISB 2001 can overcome resistance mechanisms by dual tumor targeting via binding and cytotoxicity of tumor cells with low expression of CD38 and/or BCMA.
  - + ISB 2001's architecture is optimized to support robust killing of tumor cells while limiting CD38 on-target, off-tumor activity.
  - + ISB 2001 demonstrated increased killing of tumor cells compared to BCMA-targeted T cell engagers in vitro, in vivo and ex vivo; induced complete tumor regression in humanized mouse models; and demonstrated superior potency compared to standard combination of therapies.
- The advantages of the trispecific ISB 2001 antibody was highlighted in the accompanying [News and Views article](#) written by S.R. Ruuls and P.W.H.I. Parren and was further emphasized in a [Fierce Biotech article](#) in which the mode of action of ISB 2001 and promise of IGI's BEAT® platform were described by IGI's CEO, Cyril Konto.
- In April 2023, IGI received approvals from HREC in Australia and the FDA to initiate a Phase 1 first-in-human study of ISB 2001 for the treatment of r/r MM. In April 2024, IGI received approval from DCGI to expand the clinical Phase 1 study into India. The phase 1 study is divided into a dose escalation part and a dose expansion part, with the latter being designed to meet the goals of FDA Project Optimus. First patient was dosed in November 2023 and the trial is now active in US, Australia and India, with dose expansion initiated in April 2025. Enrollment in Europe is targeted for end of Q2 2025.
- In July 2023, ISB 2001 received Orphan Drug Designation from the FDA for the treatment of MM and in April 2025, FDA also granted Fast Track designation to ISB 2001 ([press release](#)).
- IGI declared clinical Proof-of-Concept for ISB 2001 in r/r MM in July 2024, based on the data generated in the ongoing dose escalation phase, and decided to accelerate the development of this asset.
- The first clinical data of the ongoing ISB 2001 trial was presented in an oral presentation at [ASH 2024](#) on December 9<sup>th</sup>, 2024 ([press release](#)) and showed:

- + ISB 2001 is well tolerated with no dose limiting toxicities up to 1200 µg/kg, low grade cytokine release syndrome, no neurological Adverse Events or ICANs, low infection and hematological toxicity rates, no Adverse Events leading to discontinuation<sup>1</sup>
- + Early, deep and sustained responses were observed across effective dose levels (DL3 to DL7) with antimyeloma activity from 50 µg/kg (MRD negative sCR) and higher<sup>1</sup>
- + Overall Response rate (ORR) was 83% (22% Complete response (CR) or better, 50% Very Good Partial Response (VGPR) and 11% Partial Response (PR). The ORR was 75 % in patients pretreated with CAR-T or bispecific T cell engagers and 90 % in patients who had not been treated with T-cell directed therapies<sup>1</sup>
- + Dose proportional PK with long half-life supports less frequent dosing and T cell activation observed at effective doses<sup>1</sup>
- Next presentation of clinical data will be in June 2025 at [ASCO2025](#)
- ISB 2001 has been raising the interest from several global players, which has prompted the initiation of partnering discussions

<sup>1</sup>Quach H. et al., ASH2024, Oral Presentation



## **CASITAS B-LINEAGE LYMPHOMA B (CBL/B) PROGRAM**

- Casitas B-lineage lymphoma b (Cbl/b) is an E3 ubiquitin ligase that has been identified as a key inhibitor of T and NK cells activation in the absence of CD28 co-stimulation, regulate immune cells activity in PD-1, CTLA4, TIGIT etc positive cells. As an intracellular master regulator, Cbl/b inhibition may lead to robust immune cells activation in suppressed tumor microenvironment and induce strong single agent activity.
- The IND for the clinical candidate GRC 65327 was submitted to the Drugs Controller General of India (DCGI) on October 30, 2024. The meeting with the oncology subject matter expert committee (SEC) happened on December 13, 2024. The committee recommended the approval of the Phase 1 protocol with the condition of initiating the study with a 10 mg dose cohort and submitting data of the first subject of the same cohort before initiation into the second subject to the Central Drugs Standard Control Organization (CDSCO) for further deliberation by the committee. A second set of queries from DCGI SEC received on March 21, 2025, were addressed on April 23, 2025. Final reports of toxicology studies were submitted to DCGI along with the response. A formal approval of NOC is awaited.
- A poster entitled 'Discovery of GRC 65327: A Best-in-Class, Selective and potent Cbl-b E3 ligase inhibitor for the treatment of advanced solid cancers' was presented at [AACR2025](#).

## Autoimmune Diseases

IGI has two monoclonal antibody drug product candidates addressing autoimmune diseases in the pipeline. To enhance the company's focus on oncology, future development of both assets is overseen by out-licensing partners.

The first asset, ISB 880, an anti-IL-1RAP antagonist, was licensed to Almirall, S.A. in December 2021. The initiation of dosing in a Phase 1 study of ISB 880/ALM27134 was announced by Almirall in September 2022.

The second antibody, ISB 830 (telazorlimab) and its follow-on molecule ISB 830-X8, was licensed to Astria Therapeutics in October 2023. Telazorlimab is an OX40 antagonist that successfully completed a Phase 2b study in moderate to severe atopic dermatitis in 2021. Both compounds have potential across a range of autoimmune diseases.

## Assets in Autoimmune Diseases

MOLECULE MECHANISM/CLASS	POTENTIAL INDICATIONS	PHASE	STATUS
ISB 880 (ALM 27134) IL-1RAP Antagonist Monoclonal Antibody	Autoimmune Diseases	Phase 1	Licensed to Almirall S.A. in December 2021. <u>Dosing of participants in the Phase 1 study was announced by Almirall in September 2022.</u>
ISB 830 Telazolimab OX40 Antagonist Antibody	Atopic Dermatitis	Phase 2b	Licensed to Astria Therapeutics in October 2023. Successfully completed a Phase 2b study in Atopic Dermatitis.
	Other autoimmune diseases, including Rheumatoid Arthritis	U.S. IND for Rheumatoid Arthritis and other autoimmune indications is active.	
	Other autoimmune diseases, including Rheumatoid Arthritis	U.S. IND for Rheumatoid Arthritis and other autoimmune indications is active.	

### ISB 880 / ALM27134 (IL-1RAP ANTAGONIST)



IGI entered an exclusive global licensing agreement for ISB 880 in autoimmune diseases with Almirall in December 2021. Within the terms of the agreement, Almirall assumed full cost and responsibility for the global development and commercialization of the compound. IGI received an upfront payment of €20.8 million. The deal includes development and commercial milestone payments, and tiered royalties based upon future global sales. Almirall initiated a Phase I study in 2022, to evaluate the safety, pharmacokinetics, pharmacodynamics and clinical activity of the licensed asset. IGI received a milestone payment in March 2025 based on the successful phase I study.

For more information on this asset, please visit [almirall.com](https://almirall.com)

### ISB 830 (TELAZORLIMAB, OX40 ANTAGONIST)



IGI entered an exclusive global licensing agreement for ISB 830 and its follow-on ISB 830-X8 with Astria Therapeutics in October 2023.

On January 23, Astria announced initiation of a phase 1a trial of STAR0310, a potential best-in-class monoclonal antibody OX40 antagonist for the treatment of atopic dermatitis. The dosing of the first human subject triggered the payment of a development milestone to IGI.

For more information, visit <https://IGInnovate.com/contact/>