November 14, 2024

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

**Ref: Scrip Code: 532296**

**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 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 Second Quarter ended September 30, 2024.

You are requested to take the same on record.

Thanking You.

Yours faithfully,
**For Glenmark Pharmaceuticals Limited**

HARISH VINAYAK KUBER
Digitally signed by HARISH VINAYAK KUBER
Date: 2024.11.14 18:49:17 +05'30'

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

Encl: As above

**Press Release**
For Immediate Distribution

# Glenmark Pharma reports consolidated revenue growth of 7.1% and EBITDA growth of 30% YoY for Q2 FY 2024-25

**Highlights for Q2 FY 2024-25**

- *Europe Business grew by 14.6% to Rs. 6,874 Mn.*
- *India Business grew by 13.9% to Rs. 12,817 Mn.*
- *EBITDA of Rs. 6,019 Mn, with EBITDA margin of 17.5%.*
- *Profit After Tax (PAT) of Rs. 3,545 Mn with PAT margin of 10.3%.*

**Mumbai, India, November 14, 2024:** Glenmark Pharmaceuticals Ltd. (Glenmark), a research led, global pharmaceutical company, today announced its financial results for the second quarter ended September 30,2024

For the second quarter of FY 2024-25, Glenmark's consolidated revenue was at Rs. 34,338 Mn as against Rs. 32,074 Mn recording an increase of 7.1% YoY.

EBITDA was Rs. 6,019 Mn in the quarter ended September 30, 2024, as compared to Rs. 4,623 Mn in the previous corresponding quarter, registering growth of 30.2%.

Profit After Tax (PAT) for the quarter ended September 30, 2024 was at Rs. 3,545 Mn, with PAT margin of 10.3%.

**Commenting on the results, Glenn Saldanha, Chairman & Managing Director, Glenmark Pharmaceuticals Ltd. said,** "This quarter, we have maintained a strong growth trajectory, driven by robust performances in the India and Europe markets. Our flagship respiratory brand, RYALTRIS®, continues to perform well across all key regions, reaffirming its position as a leading treatment option. Additionally, we have strategically in-licensed innovative products in our priority therapeutic areas, further strengthening our commitment to addressing unmet medical needs and improving patient outcomes."

"Our novel biologic asset, ISB 2001, developed by Ichnos Glenmark Innovation (IGI), has shown promising efficacy and safety in Phase 1 trials, and we look forward to presenting these encouraging first-time data at the 66$^{th}$ American Society of Hematology (ASH) Annual Meeting next month," **he added**.

**GLENMARK PHARMACEUTICALS LTD.**

**India**

Sales from the formulation business in India in Q2 FY 2024-25 was at Rs. 12,817 Mn as against Rs. 11,252 Mn in the previous corresponding quarter, recording growth of 13.9% YoY.

**North America**

North America registered revenue from the sales of finished dosage formulations of Rs. 7,405 Mn for the quarter ended Sep 30, 2024 as against revenue of Rs. 7,498 Mn for the previous corresponding quarter, recording decline of 1.2% YoY.

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

For the second quarter of FY 2024-25, revenue from RoW was Rs. 7,041 Mn as against Rs. 7,339 Mn for the previous corresponding quarter, recording decline of 4.1% YoY.

**Europe**

Glenmark Europe's operations revenue for the second quarter of FY 2024-25, the was at Rs. 6,874 Mn as against Rs. 5,997 Mn, recording growth of 14.6% YoY.

**Creating Global Brands**

**RYALTRIS®**

- As of September 2024, marketing applications for RYALTRIS® have been submitted in more than 90 countries across the world and the product has been commercialized in 41 markets. Further, it has received approval and will be launched in 10-11 additional markets over the next few quarters
- As per IQVIA June 2024 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 strong uptake in markets where the product was recently launched across Europe and ROW regions.
- Glenmark's commercial partner in the USA, Hikma, recorded consistently better performance on a YoY basis in the second quarter, backed by strong demand and stable supply.
- Menarini, Glenmark's partner in the EU, has witnessed steady increase in market share across all its licensed markets.
- Glenmark's partner in Mainland China, Grand Pharmaceutical (China) Co. Ltd., has received acceptance of the NDA in February 2024. The Company expects approval to be received in FY 2025-26.

*Market share: Top 10 products within "R1A1 – Nasal Corticosteroids without Anti Infectives" category as per IQVIA + RYALTRIS® as of June 2024

**ENVAFOLIMAB**

- In January 2024, Glenmark announced the signing of a license agreement with Jiangsu Alphamab Biopharmaceuticals Co., Ltd (Jiangsu Alphamab) and 3D Medicines (Beijing) Co., Ltd. (3DMed) for Envafolimab for India, Asia Pacific, Middle East and Africa, Russia, CIS, and Latin America.
- Envafolimab, under the brand name ENWEIDA®, has been approved in China by the National Medical Products Administration (Chinese NMPA) in November 2021 as the global-first subcutaneous injection PD-L1 inhibitor for the treatment of adult patients with previously treated microsatellite instability-high (MSI-H) or deficient MisMatch repair (dMMR) advanced solid tumor.
- In China, Envafolimab has been officially included in the "List of Breakthrough Therapies" by the NMPA in December 2023. Up until November 2023, Envafolimab was recommended by 12 clinical guidelines in China and the US including 3 Chinese versions of the National Comprehensive Cancer Network (NCCN) guidelines for the treatment of multiple malignancies. Envafolimab has the potential to provide an effective treatment for such population across India and Emerging Markets.
- Glenmark plans to file Envafolimab in more than 20 markets in FY 2024-25 and the first market launch is expected in FY 2025-26.

**WINLEVI®**

- In Q2 FY 2023-24, Cosmo Pharmaceuticals N.V. (“Cosmo”) and Glenmark, announced the signing of distribution and license agreements for WINLEVI® (clascoterone cream 1%) in 15 European countries as well as the UK and South Africa.
- The Company is awaiting approval in its licensed markets and plans to launch WINLEVI® in FY26.

**Ichnos Glenmark Innovation**

IGI features a robust pipeline of three innovative oncology molecules targeting multiple myeloma, acute myeloid leukemia and solid tumors currently undergoing clinical trials. Two of these molecules have received orphan drug designation from the U.S. FDA. Additionally, IGI has two autoimmune disease assets that have been out licensed to leading companies.

For further updates on the pipeline and the organization, please log on to https://iginnovate.com/

--End--

**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. You can follow us on LinkedIn (Glenmark Pharmaceuticals) and Instagram (glenmark_pharma).

**For more information, please contact**

Udaykumar Murthy | corpcomm@glenmarkpharma.com | +91 9960377617

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

## Revenue Figures for Glenmark Pharmaceuticals Ltd.

*(In Rs. Million)*

| | For the second quarter ended September 30 | | | For the six months ended September 30 | | |
|---|---|---|---|---|---|---|
| | FY 2024-25 | FY 2023-24 | Growth (%) | FY 2024-25 | FY 2023-24 | Growth (%) |
| **India** | 12,817 | 11,252 | 13.9% | 24,778 | 21,945 | 12.9% |
| **North America** | 7,405 | 7,498 | -1.2% | 15,213 | 15,681 | -3.0% |
| **Europe** | 6,874 | 5,997 | 14.6% | 13,831 | 11,729 | 17.9% |
| **Rest of the World**[1] | 7,041 | 7,339 | -4.1% | 12,749 | 12,867 | -0.9% |
| **Total** | **34,137** | **32,086** | **6.4%** | **66,572** | **62,222** | **7.0%** |
| **Other Revenue** | 201 | -12 | -- | 208 | 212 | -2.2% |
| **Consolidated Revenue** | **34,338** | **32,074** | **7.1%** | **66,780** | **62,434** | **7.0%** |

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

Average conversion rate in 6M FY 2024-25 considered as INR 83.59 / USD 1.00

Average conversion rate in 6M FY 2023-24 considered as INR 82.42 / USD 1.00

USD figures are only indicative

**Review of Operations for the Quarter ended September 30, 2024**

For the second quarter of FY25, Glenmark's consolidated revenue from operations was at Rs. 34,338 Mn (USD 410 Mn) as against Rs. 32,074 Mn (USD 387.9 Mn) in the corresponding quarter last year, recording overall year-on-year (YoY) growth of 7.1%.

For the six months ended September 30, 2024, Glenmark's consolidated revenue was at Rs. 66,780 Mn (USD 798.9 Mn) as against Rs. 62,434 Mn (USD 757.5 Mn), recording an increase of 7%.

## 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 second quarter of FY25 was at Rs. 12,817 Mn (USD 153 Mn) as against Rs. 11,252 Mn (USD 136.1 Mn) in the corresponding quarter last year, recording a growth of 13.9%. The India business contribution was at 37.3% in Q2 FY25.

The Indian pharmaceutical market (IPM) continued to witness a slow-down in the overall market, however Glenmark continues to significantly outperform the IPM in terms of YoY growth. Accordingly, as per IQVIA, Glenmark's India formulation business recorded a growth of 12.7% in Q2 FY25 and 13.1% as per MAT September 2024, compared to the overall market growth of 7.6% in both Q2 FY25 and MAT September 2024. In Q2 FY25, acute respiratory market continued to witness a slow-down due to the seasonality factor; as a result, both the overall respiratory market and Glenmark's respiratory business recorded single-digit growth. Glenmark continued to outperform the overall market in both Dermatology and Cardiac therapeutic areas.

| | IPM | GLENMARK | IPM | GLENMARK |
|---|---|---|---|---|
| SUPERGROUP | VALUE GROWTH (JUL'24 - SEP'24) | VALUE GROWTH (JUL'24 - SEP'24) | VALUE GROWTH (MAT SEP'24) | VALUE GROWTH (MAT SEP'24) |
| CARDIAC | 11.9 | 15.3 | 12.0 | 23.9 |
| DERMATOLOGY | 9.3 | 19.5 | 7.8 | 13.7 |
| RESPIRATORY | 2.3 | 3.7 | 2.0 | 3.6 |
| DIABETES | 9.4 | -2.2 | 8.2 | -8.5 |

Glenmark's India business is now ranked 13$^{th}$ with a market share of 2.22% (IQVIA MAT September 2024).

The Company continues to have 9 brands in the IPM Top 300 Brands in the country on the basis of IQVIA MAT September 2024. In terms of key therapeutic areas, Glenmark is ranked 2nd in Dermatology, 3rd in Respiratory and 5th in the Cardiac segment as per IQVIA MAT September 2024.

In spite of the challenging market environment, Glenmark has improved its market share in the key therapy areas as per IQVIA MAT September 2024 data.

| | GLENMARK | |
|---|---|---|
| **SUPERGROUP** | **MARKET SHARE (%) MAT SEP'23** | **MARKET SHARE (%) MAT SEP'24** |
| CARDIAC | 5.3 | 5.9 |
| DERMATOLOGY | 7.5 | 7.9 |
| RESPIRATORY | 5.7 | 5.8 |
| DIABETES | 1.5 | 1.3 |

**LIRAFIT™**

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

**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.
- The Company has initiated promotional activities, and 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 the next 6-9 months post the receipt of the required regulatory approvals.

## INDIA – GLENMARK CONSUMER CARE (GCC)

Primary sales for GCC in Q2 FY25 was Rs. 733 Mn with a YoY growth of 15%. The Company's flagship brand Candid Powder™ delivered revenue growth YoY of 13% for Q2 FY25. The brand continued to gain market share, and recorded 57.4% share for the month of September 2024. In Q2 FY25, the Scalpe™ portfolio delivered a robust revenue growth of 40% YoY. The key variant, Scalpe Plus grew by 13% in Q2, while Scalpe PRO doubled its business and registered a 131% growth. D'Acne™ Portfolio switch was initiated in the second quarter and the brand has grown by 22% in Q2 FY25.

## NORTH AMERICA

The North America business recorded revenues from the sale of finished dosage formulations of Rs. 7,405 Mn (USD 88.4 Mn) for the second quarter of FY25 as against revenue of Rs. 7,498 Mn (USD 90.7 Mn) for the second quarter of FY24. This translates in to a YoY decline of 1.2%. For the second quarter of FY25, the North America business contribution was at 21.6%.

In the second quarter of fiscal year 2024-25, Glenmark received approval for and launched Topiramate Capsules USP (Sprinkle), 15 mg and 25 mg. In addition, Glenmark launched 3 new over-the-counter products: Adapalene Gel USP, 0.1% [Paraben Free Formulation], Cetirizine Hydrochloride Tablets USP, and Olopatadine Hydrochloride Ophthalmic Solution USP, 0.1%. Glenmark also acquired the previously approved ANDA for Acetylcysteine Injection, 6 g/30 mL (200 mg/mL) in Q2 FY25; this will be Glenmark's 8$^{th}$ commercial product in the injectable portfolio for the US market. Glenmark has also leveraged its strong development capabilities in the Respiratory therapeutic 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 has filed the ANDA for gFlovent® 44mcg pMDI in May 2024.

One ANDA was filed during the second quarter. Glenmark plans to file two ANDAs in the upcoming quarter, and the Company plans to launch 3-4 products in the upcoming quarter. Glenmark's marketing portfolio through September 30, 2024 consists of 198 generic products authorized for distribution in the U.S. market. The Company currently has 50 applications pending in various stages of the approval process with the US FDA, of which 21 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, August 2024

## EUROPE

Glenmark Europe operations' revenue for the second quarter of FY25 was at Rs. 6,874 Mn (USD 82.1 Mn) as against Rs. 5,997 Mn (USD 72.5 Mn) recording a growth of 14.6%. Europe business contributed 20% of the total revenues in Q2 FY25.

Glenmark's European operations continued their strong trajectory, driven by a robust uptick of the branded business and sustained growth across all key markets in the region. Glenmark continued to outperform the overall pharmaceutical market in the key Central and Eastern European (CEE) countries such as the Czech, Poland and Slovakia. Growth in the CEE region was also aided by 3 new product launches. The Western European business clocked double-digit growth for Q2; the branded Respiratory portfolio continues its strong trajectory. Glenmark is now ranked 14th in the generic market of Germany as per IQVIA MAT August 2024 data. Key Respiratory brands such as RYALTRIS® and Salmex® / Asthmex® continue to sustain their market share, both, in terms of volume as well as value, across the region. The Company continues to focus on sustaining the increasing contribution from the branded markets / portfolio in Europe. It is awaiting approval of four respiratory products which were filed in Q4 FY23. The Company is also planning to launch WINLEVI® in select markets of Europe in FY26.

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

For the second quarter of FY25, revenue from the ROW region was Rs. 7,041 Mn (USD 84.1 Mn) as against Rs. 7,339 Mn (USD 88.8 Mn) for the corresponding quarter last year, recording a decline of 4.1%. For the second quarter of FY25, the ROW business contribution was at 20.5%. In spite of the lack of growth in the first two quarters of FY25, Glenmark anticipates to finish the year FY25 with a high single-digit YoY growth in ROW on a constant currency basis.

As per IQVIA Q2 FY25 and MAT September 2024 data, Glenmark's Russia business recorded secondary sales growth of 16% and 19% in value, respectively. RYALTRIS® sustained its momentum and gained further market share during the quarter. Amongst the Dermatology companies in Russia, Glenmark ranks 9th as per MAT September 2024. Amongst the companies present in the Expectorants market in Russia, Glenmark continues to maintain a strong position, ranking 2nd as per MAT September 2024.

The Respiratory portfolio continued to be the key growth driver for Glenmark in the LATAM region Glenmark launched the first generic Salmeterol + Fluticasone MDI in the Brazilian market in Q1 FY25 and the product has done well post launch. RYALTRIS® was launched in the Mexican market in Q2, and is expected to be launched in another 1-2 markets in the region over the next 6 months, along with multiple other device-based respiratory products.

In the Middle East and Africa region, the Company continued to achieve secondary sales growth in key markets. Glenmark is now ranked 2nd 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, some markets witnessed slowdown due to the ongoing political and economic

challenges. New product launches in Dermatology and Respiratory are expected to contribute to growth in the upcoming quarters. RYALTRIS® continues to significantly outperform the overall market in the region.

## CREATING GLOBAL BRANDS

### RYALTRIS®

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## ICHNOS GLENMARK INNOVATION (IGI)

IGI features a robust pipeline of three innovative oncology molecules targeting multiple myeloma, acute myeloid leukemia and solid tumors currently undergoing clinical trials. Two of these molecules have received orphan drug designation from the U.S. FDA. Additionally, IGI has two autoimmune disease assets that have been out licensed to leading companies.

**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**

- ISB 2001 represents a groundbreaking approach in the fight against multiple myeloma. It is a trispecific T cell engager (TCE) that targets BCMA and CD38 on multiple myeloma (MM) cells while engaging CD3 on T cells to harness the body's immune system against the cancer. This dual targeting mechanism enhances tumor cell destruction and offers a new pathway to address the challenges faced in treating relapsed/refractory multiple myeloma.
- ISB 2001 is amongst the first trispecific antibodies developed for use in multiple myeloma. In July 2023, ISB 2001 received Orphan Drug Designation from the FDA for the treatment of MM.
- The Phase 1 first-in-human study of ISB 2001 for the treatment of r/r MM is divided into a dose escalation part and a dose expansion part. First patient was dosed in November 2023 and the trial is now active in the US, Australia and India. Dose escalation is currently still underway,

with expansion scheduled to initiate in H1 CY2025.

**ISB 2001 DATA PRESENTATION AT ASH2024**

- IGI recently announced that it will present 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 will detail results from the dose-escalation portion of the study. The abstract features data as of July 2024, including:
    - An overall response rate (ORR) of 75% (9/12) in efficacy-evaluable patients, including one (1) MRD negative stringent complete response (sCR)
    - A favorable safety and tolerability profile that showed no dose-limiting toxicities (DLTs), only one adverse event of special interest (AE) above Grade 2, and no treatment discontinuation
    - The most updated data presentation will be available at ASH2024
- IGI aims to initiate partnering discussions post ASH2024

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

## KEY OBJECTIVES FOR FY25

- **Consolidated Revenue: INR 1,35,000 – 1,40,000 million**
- **R&D Investment: 7-7.25% of total sales**
- **EBITDA Margin: ~19%**
- **Consolidated CAPEX: INR 7,000 million**
- **Target double-digit PAT margin**



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# November 2024 Update

## About IGI

Ichnos Glenmark Innovation (IGI) is an alliance between Ichnos Sciences Inc., a global fully integrated clinical-stage biotech company developing multispecifics™ in oncology, and Glenmark Pharmaceuticals Ltd. (Glenmark), with the aim to accelerate new drug discovery in cancer treatment. IGI combines Ichnos' research and development proficiencies in novel biologics with those of Glenmark's in new small molecules to continue developing cutting-edge therapy solutions that treat hematological malignancies and solid tumors. Harnessing the combined proficiency of over 150 scientists and a robust pipeline of novel molecules, this collaboration will 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.

Headquartered in New York City, IGI has research and manufacturing operations at two sites in Switzerland. As a fully integrated biotechnology company with approximately 200 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.

### Highly Experienced Leadership Team

**LEADERSHIP**

**CYRIL KONTO, M.D.**
President and Chief Executive Officer

**LIDA PACAUD, M.D.**
Chief Medical Officer

**MARIO PERRO, Ph.D.**
Head of Biologics Research

**NAGARAJ GOWDA, Ph.D.**
Head of Small Molecule Research

**ROBERTO GIOVANNINI, Ph.D.**
Chief Process & Manufacturing Officer

**DEAN THOMAS, LLM**
General Counsel

**SEBASTIEN CHENUET, Ph.D.**
Head of Business Development

**EVA YUEN**
Head of Finance

**KARISHMA SIPAHIMALANI, Ph.D.**
Head of Human Resources

**PREVIOUS EXPERIENCE**

Pfizer, Allogene, Bristol Myers Squibb, Roche, Legend Biotech, Novartis, sanofi, Aurigene Oncology, Debiopharm, Boehringer Ingelheim, glenmark

**BY THE NUMBERS**

**110+**
Years combined experience in biotech and pharmaceuticals

**30+**
Products developed or launched

**40+**
Mergers, acquisitions, IPOs and other transactions

The proprietary BEAT® technology platform[1] is one of the basis 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.

[1] Bispecific Engagement by Antibodies based on the TCR

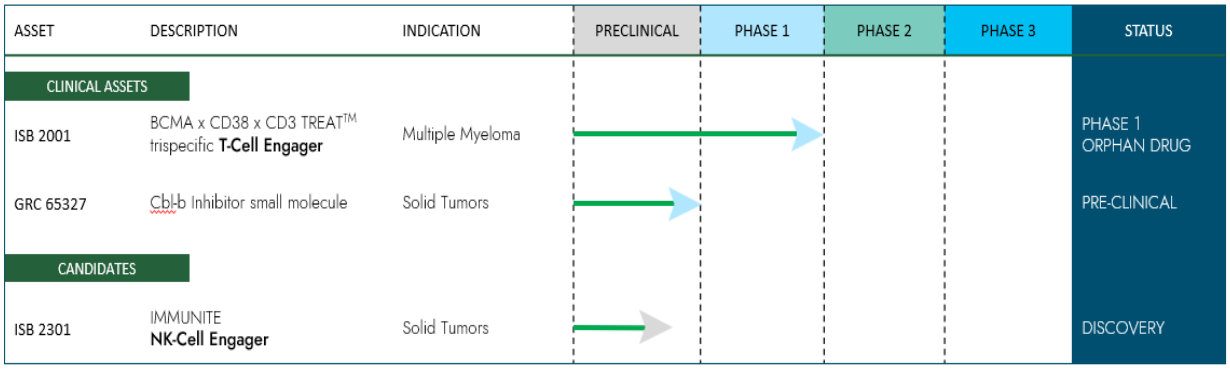
Collaboration propels innovation

# Oncology Pipeline

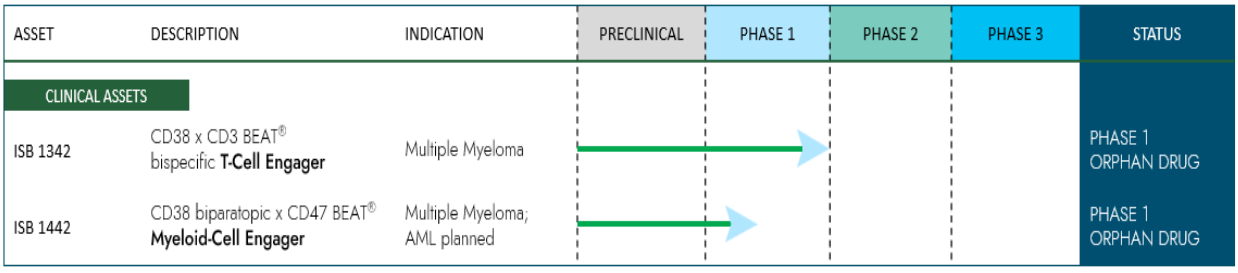
IGI's multispecific antibody pipeline consists of four assets. This includes ISB 2301 which is in the discovery stages for application in solid tumors and ISB 2001, ISB 1342 and ISB 1442, each of which are orphan drug designated by the U.S. Food and Drug Administration (FDA) and currently in Phase 1 clinical studies for relapsed/refractory multiple myeloma. Small molecule research group in India has experienced research group and facility to work on challenging targets across different classes and recently working on protein degradation. Updates of note in the last quarter are outlined below:

+ The preclinical data package for ISB 2001 was recently published in Nature Cancer
+ ISB 2001 abstract was accepted at ASH2024 for an oral presentation of the first clinical data in the section of: Multiple Myeloma: Pharmacologic Therapies: Into the Future: New Drugs and Combinations in Multiple Myeloma
+ The ISB 2001-101 clinical Ph1 study is enrolling patients rapidly and a protocol amendment was recently approved to explore two additional higher doses.
+ ISB 1442 abstract was accepted at ASH2024 for a poster presentation of the clinical data
+ The IND for the clinical candidate GRC 65327 was submitted to DCGI on October 30, 2024
+ ISB 1342 is in active discussions for out licensing in oncology and non-oncology

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




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




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 Select Oncology Drug Product Candidates

## 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 recently 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.
- At the recent Festivals of Biologics in Basel and at PEGS Europe in Barcelona, the antibody engineering, pharmacology and cell line development of ISB 2001 were presented in several presentations.
- In April 2023, Ichnos 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 expansion scheduled to initiate in H1, 2025.
- In July 2023, ISB 2001 received Orphan Drug Designation from the FDA for the treatment of MM.
- 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 has decided to accelerate the development of this asset.
- The first clinical data of the ongoing ISB 2001 trial will be presented in an oral presentation at ASH 2024 on December 9th, 2024 (press release).

Collaboration propels innovation

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

- This first-in-class biparatopic bispecific antibody targeting CD38 and CD47 was generated by scientists in IGI's 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 (ADCC) as well as complement-dependent cytotoxicity (CDC).
- After receiving approval from the HREC in Australia, the U.S. Food and Drug Administration and the Drug Controller General of India, IGI is conducting a Phase 1 / 2 first-in-human dose-finding study of ISB 1442 in relapsed/refractory multiple myeloma and the dose escalation phase is active in all three countries.
- The preclinical data package for ISB 1442, which may be viewed at this link, shows:
  + 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 and low preclinical in vivo xenograft models
  + Low on-target off-tumor binding with ISB 1442 compared to anti-CD47 mAb (hu5F9), 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 information on preclinical models in other hematologic malignancies were presented at the 2022 ASH Annual Meeting in December. Specifically, data showed the rationale for advancing to a clinical study in relapsed/refractory AML (link). ISB 1442 induces killing, including ADCP and ADCC, in AML cell lines in multiple in vitro assays. ISB 1442 also showed superior activity to daratumumab in AML cell lines having intermediate or low CD38 expression.
- ISB 1442 was granted Orphan Drug Designation for multiple myeloma by the FDA in February 2023.
- In addition to the information presented at the 2023 ASH Annual Meeting, more data will be presented at ASH 2024
- Proof of Mechanism in patients was declared based on increased macrophage-related markers among the other biomarkers changes observed.
- On November 1st, 2024, the decision was made to terminate the ISB 1442-101 study due to portfolio prioritization and ongoing development challenges with anti-CD47 therapeutics.

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

- A Phase 1, open-label, dose-escalation, first-in-human study of ISB 1342 in patients with relapsed/refractory multiple myeloma
  - The study has been paused due to pipeline strategic reprioritization and the asset is available for licensing in oncology (proof-of-mechanism and proof-of-concept have been established in RRMM, with acceptable immunogenicity on par with other bispecifics) as well as autoimmune indications, observations of depletion of B cells with the CD38 targeting has been observed during the clinical trial.
  - The Database was locked in March 2024 and all sites closed. The Clinical Study Report is targeted for Q4, 2024.
  - The first partial response in this study was observed in Cohort 109 intravenous (dose level 8 µg/kg) and additional two partial responses were observed in Cohort 110 intravenous (dose level 16 µg/kg). The responses are supported by translational data, where higher T cell activation has been observed with increasing doses.
- The primary objectives of the Phase 1 study are to:
  - Determine maximum tolerated dose and/or recommended Phase 2 dose of ISB 1342 (Part 1 dose escalation).
  - Assess the anti-myeloma activity of ISB 1342 according to the International Myeloma Working Group response criteria (Part 2 dose expansion).
- Clinical safety remains on par with earlier results presented in a poster session at the 2023 American Society of Hematology (ASH) Annual Meeting in December (link) with data cut-off October 27, 2023:
  - Observed CRS events were moderate and manageable with supportive care
  - No increased risk of infection has been observed
  - Proof-of-Mechanism with evidence of T cell activation was noted following treatment with ISB 1342
  - Further dose-escalation (to 32 and 64 µg/kg) is warranted based on the manageable safety profile, anti-myeloma activity observed, and supported by PK profile as well as T cell activation biomarkers.
- ISB 1342 was granted Orphan Drug Designation for multiple myeloma by the U.S. Food and Drug Administration.

**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 DCGI on October 30, 2024. The meeting with the oncology subject matter expert committee (SEC) is expected to happen on November 27, 2024, and the permission (DCGI CT-NOC) to initiate the clinical trial is expected before the end of December 2024.

- Activities for analytical tech transfer for API (drug substance) initiated for Ankleshwar plant for GMP batch manufacturing. GMP API batch manufacturing activities on-going at GLS. The drug substance and drug product for the Phase 1 clinical trial are expected by Q1 CY2025.

- A poster entitled 'GRC 65327, a novel small molecule selective oral Cbl-b inhibitor as IO therapy for patients with solid tumors' was presented at Society for Immunotherapy of Cancer (SITC) on 9 November 2024.

## 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 are 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)<br>IL-1RAP Antagonist<br>Monoclonal Antibody | Autoimmune Diseases | Phase 1 | Licensed to Almirall S.A. in December 2021. Dosing of participants in the Phase 1 study was announced by Almirall in September 2022. |
| ISB 830<br>Telazorlimab<br>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. | |
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## ISB 880 / ALM27134 (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 assumed full cost and responsibility for the global development and commercialization of the compound. Ichnos 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.

- For more information on this asset, please visit almirall.com

## ISB 830 (TELAZORLIMAB, OX40 ANTAGONIST)

- Ichnos entered an exclusive global licensing agreement for ISB 830 in autoimmune diseases with Astria Therapeutics in October 2023.

- Astria Therapeutics disclosed in their 10-Q form for the quarterly period ended March 31, 2024 that they anticipate submitting an investigational new drug application, or IND, to the FDA for STAR-0310 for the treatment of AD by year-end. If the IND clears, Astria Therapeutics anticipate initiating a Phase 1a clinical trial of STAR-0310 in healthy subjects in the first quarter of 2025 and reporting initial results from the Phase 1a clinical trial in the third quarter of 2025, including PK and PD data and early signals on safety and tolerability. Assuming positive results from the Phase 1a clinical trial, Astria Therapeutics plan to initiate a Phase 1b clinical trial of STAR-0310 in patients with AD in the second half of 2025 and would expect to report results from such trial in the second quarter of 2026.

- Previously, Ichnos had received FDA clearance to study Telazorlimab in seropositive autoimmune diseases (Rheumatoid Arthritis, Systemic Lupus Erythematosus, Sjogren's Syndrome, Multiple Sclerosis, Type I Diabetes Mellitus, Myasthenia Gravis).

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