February 14, 2025

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 Third Quarter ended December 31, 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: 2025.02.14 18:54:18 +05'30'

Harish Kuber
Company Secretary & Compliance Officer

Encl: As above

Press Release
For Immediate Distribution

glenmark
A new way for a new world

Glenmark Pharma reports consolidated revenue growth of 35.1%, EBITDA margin of 17.7% and PAT margin of 10.3% YoY for Q3 FY2025

Highlights for Q3 FY2025

- *India Business grew by 300.2% to Rs. 10,637 Mn.*
- *Europe Business grew by 14.8% to Rs. 7,297 Mn.*
- *RoW Business grew by 3% to Rs. 7,491 Mn.*
- *North America Business grew by 1.4% to Rs. 7,813 Mn.*
- *EBITDA of Rs. 6,002 Mn, with EBITDA margin of 17.7%.*
- *Profit After Tax (PAT) of Rs. 3,480 Mn with PAT margin of 10.3%.*

Mumbai, India, January 14, 2025: Glenmark Pharmaceuticals Ltd. (Glenmark), a research-led, global pharmaceutical company, today announced its financial results for the third quarter ended December 31 2024.

For the third quarter of FY 2025, Glenmark's consolidated revenue was at Rs. 33,876 Mn as against Rs. 25,067 Mn recording an increase of 35.1% YoY.

EBITDA was Rs. 6,002 Mn in the quarter ended December 31, 2024, with EBITDA margin of 17.7%.

Profit After Tax (PAT) for the quarter ended December 31, 2024 was at Rs. 3,480 Mn, with PAT margin of 10.3%.

Commenting on the results, Glenn Saldanha, Chairman & Managing Director, Glenmark Pharmaceuticals Ltd. said, "We delivered strong and sustained growth this quarter, driven by robust performance across the regions. Our European business continued to perform well, while our branded markets demonstrated resilient growth. Strengthening our value-chain strategy, we secured MHRA authorization for WINLEVI® in the UK, marking a pivotal step in expanding our dermatology portfolio.

Looking ahead, we expect our North America business to gain momentum from FY26 onwards, supported by our growing respiratory and injectable portfolio. Additionally, we reached a significant milestone with IGI presenting promising first clinical data from our Phase 1 study of the trispecific TREAT™ antibody, ISB 2001, at the 66th American Society of Hematology (ASH) Annual Meeting. We continue to explore strategic partnerships to advance this asset." **he added**.

GLENMARK PHARMACEUTICALS LTD.

India

Sales from the formulation business in India in Q3 FY 2025 was at Rs. 10,637 Mn as against Rs. 2,658 Mn in the previous corresponding quarter, recording growth of 300.2% YoY.

North America

North America registered revenue from the sales of finished dosage formulations of Rs. 7,813 Mn for the quarter ended Dec 31, 2024 as against revenue of Rs. 7,705 Mn for the previous corresponding quarter, recording growth of 1.4% YoY.

Asia, MEA, LATAM and RCIS Region (RoW)

For the third quarter of FY 2025, revenue from RoW was Rs. 7,491 Mn as against Rs. 7,271 Mn for the previous corresponding quarter, recording decline/growth of 3% YoY. The reported growth for the ROW region during the quarter was impacted due to the adverse currency movements in some of the key markets.

Europe

Glenmark Europe's operations revenue for the third quarter of FY 2025, that was at Rs. 7,297 Mn as against Rs. 6,357 Mn, and recording growth of 14.8% YoY.

CREATING GLOBAL BRANDS:

RYALTRIS®

- As of December 2024, marketing applications for RYALTRIS® have been submitted in more than 90 countries across the world and the product has been commercialized in 43 markets. Further, it is expected to be launched in 12-15 additional markets over the next few quarters
- As per IQVIA September 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 decent performance on a YoY basis in the third quarter, backed by stable supply.
- Menarini, Glenmark's partner in the EU, has witnessed 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 September 2024.
- Glenmark's partner in Mainland China, Grand Pharmaceutical (China) Co. Ltd., expects to receive the approval sometime in FY26.

*Market share: Top 10 products within "R1A1 – Nasal Corticosteroids without Anti Infectives" category as per IQVIA + RYALTRIS® as of September 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. Envafolimab has the potential to provide an effective treatment for such population across India and Emerging Markets.
- In China, Envafolimab has been officially included in the "List of Breakthrough Therapies" by the NMPA in December 2023.
- Envafolimab is currently being investigated in clinical trials for additional cancer indications, including non-small cell lung cancer
- Glenmark plans to file Envafolimab in more than 20 markets in FY25 and the first market launch is expected in FY26.

WINLEVI®

- In Q2 FY24, 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 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 awaiting approval in its other licensed markets and plans to launch WINLEVI® in FY26.

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

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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. Scrip 100 positions Glenmark amongst the Top 100 biopharmaceutical companies ranked by Pharmaceutical Sales in 2023; while Generics Bulletin places it in the Top 50 Generics and biosimilar companies ranked by sales in 2024. 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 3.3 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 Third Quarter of FY 2024-25

Revenue Figures for Glenmark Pharmaceuticals Ltd.

(In Rs. Million)

	For the third quarter ended December 31			For the nine months ended December 31		
	FY 2024-25	FY 2023-24	Growth (%)	FY 2024-25	FY 2023-24	Growth (%)
India	10,637	2,658	300.2%	35,415	24,603	43.9%
North America	7,813	7,705	1.4%	23,026	23,386	-1.5%
Europe	7,297	6,357	14.8%	21,128	18,086	16.8%
Rest of the World[1]	7,491	7,271	3.0%	20,240	20,138	0.5%
Total	**33,237**	**23,991**	**38.5%**	**99,809**	**86,213**	**15.8%**
Other Revenue	638	1,076	-40.7%	846	1,289	-34.3%
Consolidated Revenue	**33,876**	**25,067**	**35.1%**	**1,00,655**	**87,501**	**15.0%**

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

Average conversion rate in 9M FY 2024-25 considered as INR 83.88 / USD 1.00

Average conversion rate in 9M FY 2023-24 considered as INR 82.69 / USD 1.00

USD figures are only indicative

Review of Operations for the Quarter ended December 31, 2024

For the third quarter of FY25, Glenmark's consolidated revenue from operations was at Rs. 33,876 Mn (USD 401.1 Mn) as against Rs. 25,067 Mn (USD 300.7 Mn) in the corresponding quarter last year, recording overall year-on-year (YoY) growth of 35.1%.

For the nine months of FY25, Glenmark's consolidated revenue was at Rs. 1,00,655 Mn (USD 1,200.0 Mn) as against Rs. 87,501 Mn (USD 1,058.2 Mn), recording a YoY growth of 15.0%.

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 third quarter of FY25 was at Rs. 10,637 Mn (USD 125.8 Mn) as against Rs. 2,658 Mn (USD 31.3 Mn) in the corresponding quarter last year, recording a growth of 300.2%. The India business contribution was at 31.4% in Q3 FY25.

In terms of secondary sales, Glenmark continues to significantly outperform the IPM in terms of YoY growth. As per IQVIA, Glenmark's India formulation business recorded a growth of 9.6% in Q3 FY25 and 12.3% as per MAT December 2024, compared to the overall market growth of 7.2% in Q3 FY25 and 7.4% in MAT December 2024. Glenmark continued to outperform the overall market in its key therapeutic areas like Dermatology and Cardiac therapeutic areas.

	IPM	GLENMARK	IPM	GLENMARK
SUPERGROUP	VALUE GROWTH (OCT'24 - DEC'24)	VALUE GROWTH (OCT'24 - DEC'24)	VALUE GROWTH (MAT DEC'24)	VALUE GROWTH (MAT DEC'24)
CARDIAC	11.8	12.0	12.4	21.1
DERMATOLOGY	10.4	20.7	9.6	17.6
RESPIRATORY	4.4	2.2	1.6	-0.4
DIABETES	9.1	-2.6	8.8	-4.1

Glenmark's India business is now ranked 13th with a market share of 2.23% (IQVIA MAT December 2024). The Company now has 10 brands in the IPM Top 300 Brands in the country on the basis of IQVIA MAT December 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 December 2024.

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

	GLENMARK	
SUPERGROUP	MARKET SHARE (%) MAT DEC'23	MARKET SHARE (%) MAT DEC'24
CARDIAC	5.4	5.9
DERMATOLOGY	7.5	8.0
RESPIRATORY	5.8	5.7
DIABETES	1.4	1.3

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 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.
- 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 3-4 months post the receipt of the required regulatory approvals.

INDIA – GLENMARK CONSUMER CARE (GCC)

Primary sales for GCC in Q3 FY25 was Rs. 566 Mn with a YoY growth of 13%. The Company's flagship brand Candid Powder™ gained market share as per IQVIA MAT December 2024 to take the brand market share to 55.1%. In Q3 FY25, the Scalpe™ portfolio delivered a robust revenue growth of 40% YoY. The key variant, Scalpe Plus grew by 24% as per IQVIA MAT December 2024 with a market share gain of 1.5%, while Scalpe

PRO registered a 122% growth. La Shield™ portfolio delivered growth of 13.5% as on MAT December 2024 in IQVIA.

NORTH AMERICA

The North America business recorded revenues from the sale of finished dosage formulations of Rs. 7,813 Mn (USD 92.5 Mn) for the third quarter of FY25 as against revenue of Rs. 7,705 Mn (USD 92.6 Mn) for the third quarter of FY24. This translates in to a YoY growth of 1.4%. For the third quarter of FY25, the North America business contribution was at 23.1%.

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 third quarter of fiscal year 2024-25, Glenmark launched Travoprost Ophthalmic Solution USP, 0.004% and Lacosamide Oral Solution, 10 mg/mL. One ANDA was filed during the quarter; and Glenmark plans to file one additional ANDA in the upcoming quarter.

Glenmark has 8 commercial 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 has 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 December 31, 2024 consists of 201 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 22 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, December 2024

EUROPE

Glenmark Europe operations' revenue for the third quarter of FY25 was at Rs. 7,297 Mn (USD 86.4 Mn) as against Rs. 6,357 Mn (USD 76.4 Mn) recording a growth of 14.8%. Europe business contributed 21.5% of the total revenues in Q3 FY25.

The branded business in Glenmark's European operations continued its trajectory, driven by sustained growth across all key markets in the region. While the overall CEE region faced some challenges in terms of

growth particularly due to seasonality, RYALTRIS® continued to gain market share across all countries wherein the product has been launched. The branded Respiratory portfolio in Western European business sustained its growth momentum. 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. Glenmark is now ranked 13th in the generic market of Germany as per IQVIA MAT November 2024 data. 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 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 as well as select markets of Europe in FY26.

ROW REGION (RCIS, LATAM, MEA & APAC)

For the third quarter of FY25, revenue from the ROW region was Rs. 7,491 Mn (USD 88.8 Mn) as against Rs. 7,271 Mn (USD 87.4 Mn) for the corresponding quarter last year, recording a growth of 3.0%. For the third quarter of FY25, the ROW business contribution was at 22.1%. The reported growth for the ROW region during the quarter was impacted due to the adverse currency movements in some of the key markets.

As per IQVIA MAT December 2024 data, Glenmark's Russia business recorded secondary sales growth of 16.6%. RYALTRIS® sustained its momentum and gained further market share during the quarter. In Dermatology segment Glenmark demonstrated growth of 20.7% in value vs overall retail market growth of 16.8% in value as per IQVIA MAT December 2024. Amongst the Dermatology companies in Russia, Glenmark ranks 9th as per MAT December 2024. Amongst the companies present in the Expectorants market in Russia, Glenmark continues to maintain a strong position, ranking 2nd as per MAT December 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. The Company also received approval for Salmeterol + Fluticasone DPI in Mexico, further augmenting its portfolio in the market. RYALTRIS® was launched in the Mexican market in Q2 FY25, and has since then gained 3% share in a short time span. RYALTRIS® is expected to be launched in other markets of the region over the next 6 months.

In the Middle East and Africa region, the Company continued to achieve secondary sales growth in key markets. Glenmark continues to be 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. Glenmark also witnessed strong growth in the Saudi Arabian market during the third quarter, on the back of multiple new product launches including RYALTRIS®.

In the Asia region, key markets such as Malaysia and Sri Lanka recorded double-digit secondary sales growth during the quarter. 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 December 2024, marketing applications for RYALTRIS® have been submitted in more than 90 countries across the world and the product has been commercialized in 43 markets. Further, it is expected to be launched in 12-15 additional markets over the next few quarters
- As per IQVIA September 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.
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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 as mentioned below:

- **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 trispecific 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 the cancer. This dual targeting mechanism enhances tumor cell destruction and offers a new pathway to address the challenges faced in treating r/r MM.
- ISB 2001 is amongst the first trispecific antibodies developed for use in MM and received Orphan Drug Designation from the FDA in July 2023.
- 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 CY 2025.
- 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 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.

- Twenty heavily pre-treated patients with r/r MM were enrolled as of October 1, 2024. **These patients had received a median of 6 prior lines of therapy**. About half of patients (n=9) had

received bispecific antibodies, with other prior therapies including anti-BCMA targeted therapies (n=8), and CAR-T cell therapies (n=2)

- **ISB 2001 showed a favourable safety profile in patients with heavily pre-treated r/r MM**. ISB 2001 is well tolerated with no dose limiting toxicities up to 1200 µg/kg, low grade cytokine release syndrome and no Adverse Events leading to discontinuation.
- **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 pre-treated with CAR-T or bispecific TCEs** and 90% in patients who had not been treated with TCE therapies.
- **16 patients (80%) remained on treatment at data cut-off.**

IGI has initiated partnering discussions post the ASH conference presentation and the Company aims to conclude a partnership in CY 2025. Further data from the Phase 1 dose escalation study will also be presented at the American Society of Clinical Oncology (ASCO) 2025 conference in June 2025.

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

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February 2025 Update

About IGI

IGI Inc., 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 https://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 150 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.

The proprietary BEAT® technology platform[1] 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.

Oncology Pipeline

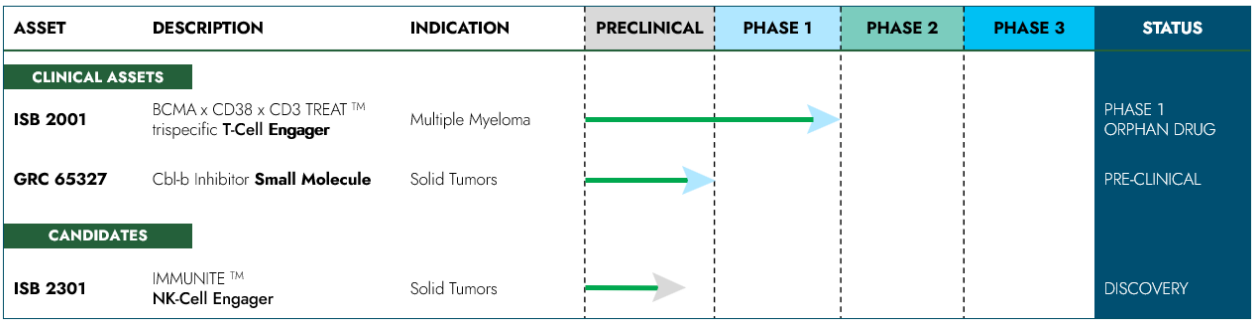
IGI's multispecific antibody pipeline consists of three assets. This includes ISB 2301 which is in the discovery stage for application in solid tumors, ISB 2001 and ISB 1442, which has orphan drug designated by the U.S. Food and Drug Administration (FDA). ISB 2001 is currently in Phase 1 clinical

[1] Bispecific Engagement by Antibodies based on the TCR

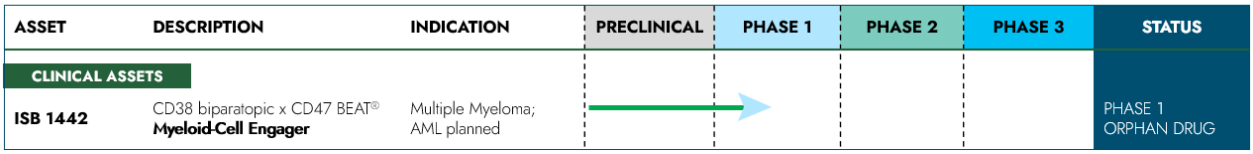
study for relapsed/refractory multiple myeloma. ISB 1442 development has been discontinued and the asset prepared for out-licensing. GRC 65327 (Cbl-b inhibitor) is awaiting regulatory approval for initiating clinical development in India for solid tumors. Updates of note in the last quarter are outlined below:

+ ISB 2001 abstract was accepted at ASH2024 and presented in 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 ISB 2001 ASH Presentation.
+ ISB 2001 continues to enroll fast in the escalation phase and expansion on track to start in H1, 2025.
+ ISB 1442 abstract was accepted and presented at ASH2024 as a poster presentation of the clinical data.

Oncology-Focused Pipeline to Drive Long-Term Value Growth



Partnering-Ready Asset 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 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.
- At Festivals of Biologics in Basel in October 2024 and at PEGS Europe in Barcelona in November 2024, the antibody engineering, pharmacology and cell line development of ISB 2001 were presented in several presentations.
- 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 the 9th and last dose level being evaluated in the dose escalation phase. The dose expansion is scheduled to be initiated 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 was presented in an oral presentation at ASH 2024 on December 9th, 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.
  - + 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
  - + 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.
  - + Dose proportional PK with long half-life supports less frequent dosing and T cell activation observed at effective doses

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 were presented at ASH 2024 and a publication describing the molecular architecture of the molecule was published in mAbs.
- 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 discontinue the ISB 1442-101 study due to portfolio prioritization and make this program available for licensing.

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. Queries from DCGI SEC received on January 7, 2025, were addressed on January 9, 2025. 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 formal approval of NOC is awaited.
- Drug substance and drug product manufacturing activities will be initiated before the Phase 1 study starts.
- An abstract 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 submitted to the AACR 2025 and confirmation expected by mid-February 2025.
- 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 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. Dosing of participants in the Phase 1 study was announced by Almirall in September 2022.
ISB 830 Telazorlimab 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)

- 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.

- For more information on this asset, please visit 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. This would trigger the payment of a development milestone to IGI upon dosing of the first human subject.

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