August 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 First Quarter ended June 30, 2025.

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: 2025.08.14 17:34:40 +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 Pharmaceuticals announces Q1FY26 results

Highlights for Q1FY26

- *India Business grew by 3.7% YoY to Rs. 12,399 Mn*
- *North America Business grew by 8.9% QoQ to Rs. 7,780 Mn*
- *Emerging Markets Business grew by 0.2% YoY to Rs. 5,721 Mn*
- *Europe Business revenue at Rs. 6,678 Mn*
- *EBITDA of Rs. 5,805 Mn, with an EBITDA margin of 17.8%.*
- **Adjusted Profit After Tax (PAT) of Rs. 3,129 Mn with an adjusted PAT margin of 9.6%.*

Mumbai, India, August 14, 2025: Glenmark Pharmaceuticals Ltd. (Glenmark), a research-led, global pharmaceutical company, today announced its financial results for the first quarter ended June 30, 2025.

For the first quarter of FY26, Glenmark's consolidated revenue was Rs. 32,644 Mn as against Rs. 32,442 Mn, recording an increase of 0.6% YoY.

EBITDA was Rs. 5,805 Mn in the quarter that ended June 30, 2025, as compared to Rs. 5,607 Mn in the previous corresponding quarter, with an EBITDA margin of 17.8%.

*Adjusted Profit After Tax (PAT) for the quarter ended June 30, 2025, was at Rs 3,129 Mn, with an adjusted PAT margin of 9.6%.

Commenting on the results, Glenn Saldanha, Chairman & Managing Director, Glenmark Pharmaceuticals Ltd., said, *"In Q1FY26, our U.S. business delivered QoQ growth, driven by a combination of injectable and partnered products launches. Our Europe and Emerging markets businesses have recorded >25% CAGR and >10% CAGR respectively over the last three years, and we expect the region to deliver a double-digit growth from the second quarter onwards. The recent IGI-AbbVie global licensing agreement for ISB 2001 is a strong validation of our innovation capabilities. We remain confident in our strategy to drive growth across our markets, while advancing our branded, specialty, and innovative products to deliver long-term value for our stakeholders."*

REGION-SPECIFIC UPDATE

India

Sales from the formulation business in India in Q1FY26 were at Rs. 12,399 Mn as against Rs. 11,962 Mn in the previous corresponding quarter, recording growth of 3.7% YoY.

North America

North America business registered revenue from the sales of Rs. 7,780 Mn for the quarter ended June 30, 2025, as against revenue of Rs. 7,146 Mn for the fourth quarter of FY25, recording growth of 8.9% QoQ, owing to share gain in injectable product launches and partnered products.

Emerging Markets (RCIS, LATAM, MEA & APAC)

For the first quarter of FY26, revenue from emerging markets was Rs. 5,721 Mn as against Rs. 5,708 Mn for the previous corresponding quarter, registering growth of 0.2% YoY. The company continues to anticipate double-digit growth on a constant currency basis.

Europe

Revenue for the first quarter of FY26 was Rs. 6,678 Mn as against Rs. 6,957 Mn, recording a decline of 4.0% YoY.

CREATING GLOBAL BRANDS

RYALTRIS®

As of June 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

QiNHAYO™ (ENVAFOLIMAB)

Glenmark has filed QiNHAYO in ~15 markets in FY25; the first market launch is expected in FY26.

WINLEVI® PARTNERED WITH COSMO

Glenmark received approval from the Medicines and Healthcare Products Regulatory Agency (MHRA) to market WINLEVI® in the United Kingdom. WINLEVI® is launched in the UK and is expecting approval in other European markets by the end of FY26.

ICHNOS GLENMARK INNOVATION (IGI)

During the quarter, IGI presented promising full dose-escalation results from its Phase 1 TRIgnite-1 study of ISB 2001, an investigational first-in-class BCMA × CD38 × CD3-targeting trispecific antibody for the treatment of patients with relapsed or refractory multiple myeloma (RRMM) at the American Society of Clinical Oncology (ASCO) 2025 Annual Meeting. IGI also announced its Global Commercialization Strategy for ISB 2001, following its landmark partnership with AbbVie. The ISB 2001 partnership validates IGI's multi-specific platform technology and positions it as a leading biotech company at the forefront of innovation in Oncology while also helping Glenmark to further expand its Oncology franchise in Emerging Markets.

**Note: Adjusted for the exceptional item related to the US litigation settlement as highlighted in the financial 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. You can follow us on LinkedIn (Glenmark Pharmaceuticals) and Instagram (glenmark_pharma).

For more information, please contact

Priyanka Chavda | corpcomm@glenmarkpharma.com | +91 96193 78489
Adfactors PR | glenmark@adfactorspr.com | +91 88502 91322

Management Discussion & Analysis
for the First Quarter of FY 2025-26

Revenue Figures for Glenmark Pharmaceuticals Ltd.

(In INR Million)

	For the first quarter ended June 30		
	FY 2025-26	**FY 2024-25**	**Growth (%)**
India	12,399	11,962	3.7%
North America	7,780	7,808	-0.4%
Europe	6,678	6,957	-4.0%
Emerging Markets[1]	5,721	5,708	0.2%
Total	**32,578**	**32,435**	**0.4%**
Other Revenue	66	7	848.4%
Consolidated Revenue	**32,644**	**32,442**	**0.6%**

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

Average conversion rate in 3M FY 2025-26 considered as INR 85.54 / USD 1.00

Average conversion rate in 3M FY 2024-25 considered as INR 83.42 / USD 1.00

USD figures are only indicative

Review of Operations for the Quarter ended June 30, 2025

For the first quarter of FY26, Glenmark's consolidated revenue from operations was at Rs. 32,644 Mn (USD 381.6 Mn) as against Rs. 32,442 Mn (USD 388.9 Mn) in the corresponding quarter last year, recording overall year-on-year (YoY) growth of 0.6%.

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 Q1 FY26 was at Rs. 12,399 Mn (USD 145 Mn) as against Rs. 11,962 Mn (USD 143.4 Mn) in the corresponding quarter last year, recording a growth of 3.7%. While Glenmark continued to deliver robust growth across Cardiac, Respiratory and Dermatology therapy areas, reported growth during the quarter was impacted on account of the discontinuation of tail-end brands announced in Q4 FY25 and underperformance in the Diabetes segment.

Glenmark's India business continued to outperform the overall industry in terms of secondary sales growth. As per IQVIA June 2025 data, Glenmark's India formulation business recorded growth of 15.1% in the first quarter, and 11.8% as of MAT June 2025. In comparison, the Indian Pharmaceutical Market (IPM) grew at 8.5% in the first quarter and 7.7% as of MAT June 2025. Glenmark continues to outperform the market in the key therapy areas of Cardiac, Dermatology and Respiratory as shown in the table below:

	IPM		GLENMARK	
SUPERGROUP	VALUE GROWTH % (MAT JUNE'25)	VALUE GROWTH % (APR'25-JUNE'25)	VALUE GROWTH % (MAT JUNE'25)	VALUE GROWTH % (APR'25-JUNE'25)
CARDIAC	11.6	12.3	14.3	18.8
DERMATOLOGY	8.3	5.8	16.7	10.8
RESPIRATORY	5.2	12.0	7.1	20.3
DIABETES	8.4	8.4	-4.1	-2.4

Glenmark's India business continues to be ranked 13th with a market share of 2.3% (IQVIA MAT June 2025). The Company is ranked 2nd in the Dermatology segment, 3rd in the Respiratory segment and 5th in the Cardiac segment as per IQVIA MAT June 2025 data. The Company continues to have 10 brands in the IPM Top 300 Brands in the country as per IQVIA MAT June 2025. Glenmark has improved its market share in the key therapy areas on the back of higher growth compared to the overall industry, as noted in the table below:

	GLENMARK	
SUPERGROUP	MARKET SHARE % MAT JUNE'24	MARKET SHARE % MAT JUNE'25
CARDIAC	5.8	6.0
DERMATOLOGY	7.7	8.3
RESPIRATORY	5.7	5.8
DIABETES	1.3	1.2

TEVIMBRA® (TISLELIZUMAB) & BRUKINSA® (ZANUBRUTINIB) (PARTNERED WITH BEONE)

- Glenmark and BeOne Medicines entered into an agreement for marketing and distribution of Tislelizumab and Zanubrutinib in India in May 2024.
- Glenmark launched both these products under the respective brand names TEVIMBRA® and BRUKINSA® in Q1 FY26
- These launches mark an important milestone in expanding the innovative Oncology portfolio and provide access to patients across multiple solid tumours and hematological malignancies.
- The Company expects these two brands to gain momentum and meaningfully contribute to the India business growth over the next 2-3 years.

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 with clear market leadership position.
- The Company also plans to launch other GLP-1 agonists soon.

INDIA – GLENMARK CONSUMER CARE (GCC)

The Consumer Care business of the Company operates in the Indian consumer healthcare market, with a primary focus on over-the counter (OTC) products mainly in the Dermatology segment and leading brands such as Candid®, La Shield®, Scalpe®, Episoft®, & Elovera®. The business is well-positioned for sustained growth, supported by rising consumer awareness and increasing adoption of self-care solutions. Primary

sales for GCC recorded a YoY growth of ~20%. Candid Powder continues to lead the category with >60% market share. La Shield portfolio delivered growth of 17.6% while Scalpe portfolio delivered a high growth of 168.6% in Q1 FY26.

NORTH AMERICA

The North America business registered revenue of Rs. 7,780 Mn (USD 91 Mn) for the first quarter of FY26 as against revenue of Rs. 7,146 Mn (USD 82.4 Mn) for the fourth quarter of FY25. This translates into a quarter-on-quarter (QoQ) growth of 8.9%. Despite a challenging environment, the Company recorded QoQ growth on the back of gaining share in injectable product launches and partnered products.

In the first quarter of fiscal year 2025-26, Glenmark launched 3 products: Mixed Amphetamines IR Tablets (generic to Adderall®), Epinephrine Injection USP, 1 mg/mL (Ampules) and Olopatadine Hydrochloride Ophthalmic Solution USP, 0.2% (OTC). While the company did not file any new ANDAs with the U.S. FDA, Glenmark plans to file one application in the forthcoming quarter.

Glenmark is building out a large commercial portfolio of injectable products through partnerships. The Company expects approval of its generic Respiratory ANDAs starting H2 FY26. Glenmark is also working on filing the ANDA for the other two strengths of gx Flovent®, as well as other Respiratory products currently in the pipeline. The Company also continues to augment its commercial portfolio through partnered product launches.

Glenmark's marketing portfolio through June 30, 2025, consists of 208 generic products[1] authorized for distribution in the U.S. market. The Company currently has 52 applications pending in various stages of the approval process with the US FDA, of which 24 are Paragraph IV applications.

The Company's subsidiary, Glenmark Pharmaceuticals Inc., USA, is named in multiple antitrust and consumer protection lawsuits, including class actions, consolidated in the Eastern District of Pennsylvania, U.S. These relate to industry-wide allegations concerning price-fixing, market allocation, and related anticompetitive conduct. Plaintiffs include putative classes of direct purchasers, end-payers, and indirect purchasers of generic drugs, as well as numerous private, direct-action plaintiffs. Glenmark USA continues to deny all allegations and has been defending these matters vigorously. With a view to resolve this dispute and avoid uncertainty, Glenmark USA has agreed to enter into a settlement with the putative direct purchaser class, for a total of USD 37.75 Mn. The settlement is subject to approval by the court overseeing the litigation. The settlement is payable in two instalments, with USD 11.1 Mn due after preliminary approval by the Court and the second payment, USD 26.65 Mn, due on or before April 1, 2026. The settlement makes clear that Glenmark USA denies each and every one of the allegations against it and the settlement is not on the basis of Glenmark USA having conceded or admitted any liability or illegality.

[1]All brand names and trademarks are the property of their respective owners. IQVIA National Sales Perspectives: Retail and Non-Retail, May 2024

EUROPE

Glenmark's Europe business has recorded >25% CAGR over the last 3 years and gained significant scale across branded products. Glenmark Europe operations' revenue for the first quarter of FY26 was Rs. 6,678 Mn (USD 78.1 Mn) as against Rs. 6,957 Mn (USD 83.4 Mn) in Q1 FY25, recording a YoY decline of 4.0%. The Company anticipates Europe region returning to double-digit growth from the second quarter onwards and expects to record double-digit growth in FY26.

During the quarter, branded business growth, particularly in the Respiratory segment, remained strong. The branded Respiratory portfolio, including RYALTRIS®, continued to grow on a monthly basis across own and partnered markets. The Company continues to focus on sustaining the increasing contribution from the branded markets / portfolio in Europe, particularly from the pending Respiratory product launches. The Company has launched WINLEVI® in the UK and is planning to launch in other European markets by end of FY26.

EMERGING MARKETS (RCIS, LATAM, MEA & APAC)

Glenmark's EM business has recorded ~10% CAGR over the last three years and recorded strong performance across all the EM regions particularly in Dermatology and Respiratory. For the first quarter of FY26, revenue from the Emerging Markets (EM) region was Rs. 5,721 Mn (USD 66.9 Mn) as against Rs. 5,708 Mn (USD 68.4 Mn) for the corresponding quarter last year, recording a YoY growth of 0.2%. While the first quarter was affected by lower seasonal demand in some LATAM markets, the rest of the EM markets grew by 9% in the first quarter. The Company continues to anticipate double-digit growth in FY26 on a constant currency basis.

As per IQVIA data, Glenmark Russia secondary sales recorded growth of 21% and 11% in Q1 FY26 and MAT June 2025. In terms of key therapeutic areas, Glenmark recorded growth of 17.4% in value in the Dermatology segment versus the overall market growth of 15% as per IQVIA MAT June 2025. Glenmark continues to rank 9th amongst the Dermatology companies and continues to be ranked 2nd in the Respiratory expectorants market in Russia as per IQVIA MAT June 2025. Key brands such as RYALTRIS®, ASCORIL™ and CANDIBIOTIC™ continue to gain and sustain high market share in their respective segments.

Glenmark's LATAM region witnessed some challenges in Q1 FY26 mainly due to the lower seasonal demand in key markets such as Mexico. Glenmark maintained its top 10 rank amongst the companies in the covered

market of the chronic respiratory segment in Brazil as per IQVIA MAT June 2025. Glenmark has launched multiple differentiated products in the Respiratory segment in the region, which should help business growth in future quarters. RYALTRIS® has been launched in Mexico and is awaiting approval in Brazil.

In the Middle East and Africa regions, the Company witnessed double-digit growth in secondary sales across major markets. RYALTRIS® continues to be the leading nasal spray for Allergic Rhinitis in South Africa and has seen a successful launch in other key markets of the region. Glenmark continues to be ranked 3rd in the overall pharmaceutical market in Kenya.

The Asia-Pacific region for Glenmark recorded a subdued performance in the first quarter. Key markets in the region, such as Malaysia, the Philippines, and Sri Lanka recorded high-single digit secondary sales growth during the first quarter. RYALTRIS® continues to do well across the Asia region and Glenmark remains one of the leading Dermatology companies in the APAC region.

CREATING GLOBAL BRANDS

RYALTRIS®

- As of June 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 June 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 EM 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 June 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 June 2025

QiNHAYO™ (ENVAFOLIMAB)

- Glenmark has filed QiNHAYO 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 has also initiated a global multi-center Phase 3 study in neo-adjuvant / adjuvant NSCLC

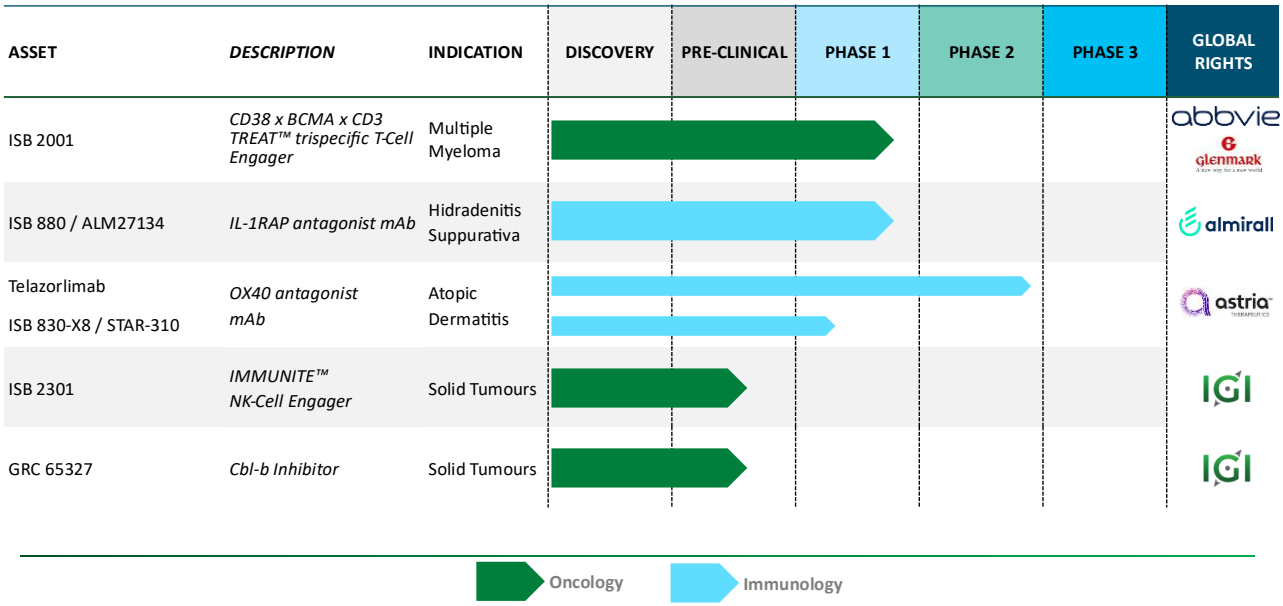
WINLEVI® PARTNERED WITH COSMO

- The Company announced that it has received approval from the Medicines and Healthcare Products Regulatory Agency (MHRA) to market WINLEVI® in the United Kingdom
- The Company has launched WINLEVI® in the UK and is expecting approval in other European markets by end of FY26

ICHNOS GLENMARK INNOVATION (IGI)

IGI features a robust pipeline of 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:

Diversity Of Immune Cell Engagement And Indications Across Hematologic And Solid Tumours



During the quarter, IGI presented promising full dose-escalation results from its Phase 1 TRIgnite-1 study of ISB 2001, an investigational first-in-class BCMA × CD38 × CD3-targeting trispecific antibody for

the treatment of patients with relapsed or refractory multiple myeloma (RRMM). These data, presented as a rapid oral presentation (Abstract #7514) at the American Society of Clinical Oncology (ASCO) 2025 Annual Meeting, demonstrated a sustained overall response rate (ORR) of 79% and a high complete/stringent complete response (CR/sCR) rate of 30% across seven active dose levels (≥ 50 µg/kg) in a heavily pretreated patient population, with a favorable safety profile. The ORR was 74% in all treated patients, including two patients treated at lower dose levels.

Recently, IGI also announced its Global Commercialization Strategy for ISB 2001, following its landmark partnership with AbbVie. Under the terms of agreement, IGI partnered with AbbVie and granted exclusive rights to globally develop, manufacture, and commercialize ISB 2001 across North America, Europe, Japan, and Greater China while Glenmark Pharmaceuticals will develop, manufacture and lead commercialization of ISB 2001 across Emerging Markets including the rest of Asia, Latin America, the Russia/CIS region, the Middle East, Africa, Australia, New Zealand and South Korea. The ISB 2001 partnership validates IGI's multi-specific platform technology and positions it as a leading biotech company at the forefront of innovation in Oncology while also helping Glenmark to further expand its Oncology franchise in Emerging Markets.

#####

August 2025 Update

About Ichnos Glenmark Innovation (IGI)

IGI, Inc. is a global, fully integrated clinical-stage biotechnology company focused on developing innovative biologics in oncology. Headquartered in New York, NY, IGI is advancing a robust pipeline of novel, first-in-class Multispecifics™ aimed at addressing complex diseases and treating patients holistically. Powered by its proprietary BEAT® technology platform, IGI is committed to delivering breakthrough, curative therapies to improve and extend the lives of patients battling hematological malignancies and solid tumors. For more information, visit IGInnovate.com.

At IGI, there are three engines of innovation. Company headquarters in the United States in New York City, a biologics research center in Lausanne, Switzerland, and early discovery center in Navi Mumbai, Maharashtra, India.

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.

[1]Bispecific Engagement by Antibodies based on the TCR

Oncology and Immunology Pipeline

IGI's multispecific antibody and small molecule immune modulator pipeline for oncology, consists of three assets. This includes ISB 2001 (BCMA x CD38 x CD3), 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 Part 2 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. Updates of note in the last quarter are outlined below:

+ In a major strategic milestone (press release), IGI entered into a global licensing agreement with AbbVie for its lead asset, ISB 2001, a first-in-class trispecific T cell engager currently in Phase 1 clinical development for relapsed/refractory multiple myeloma. Under the terms of the agreement, AbbVie will receive exclusive rights to develop, manufacture, and commercialize ISB 2001 across North America, Europe, Japan, and Greater China, for oncology and autoimmune diseases. Subject to regulatory clearance, IGI will receive an upfront payment of $700 million and is eligible to receive up to $1.225 billion in development, regulatory, and commercial milestone payments, along with tiered, double-digit royalties on net sales

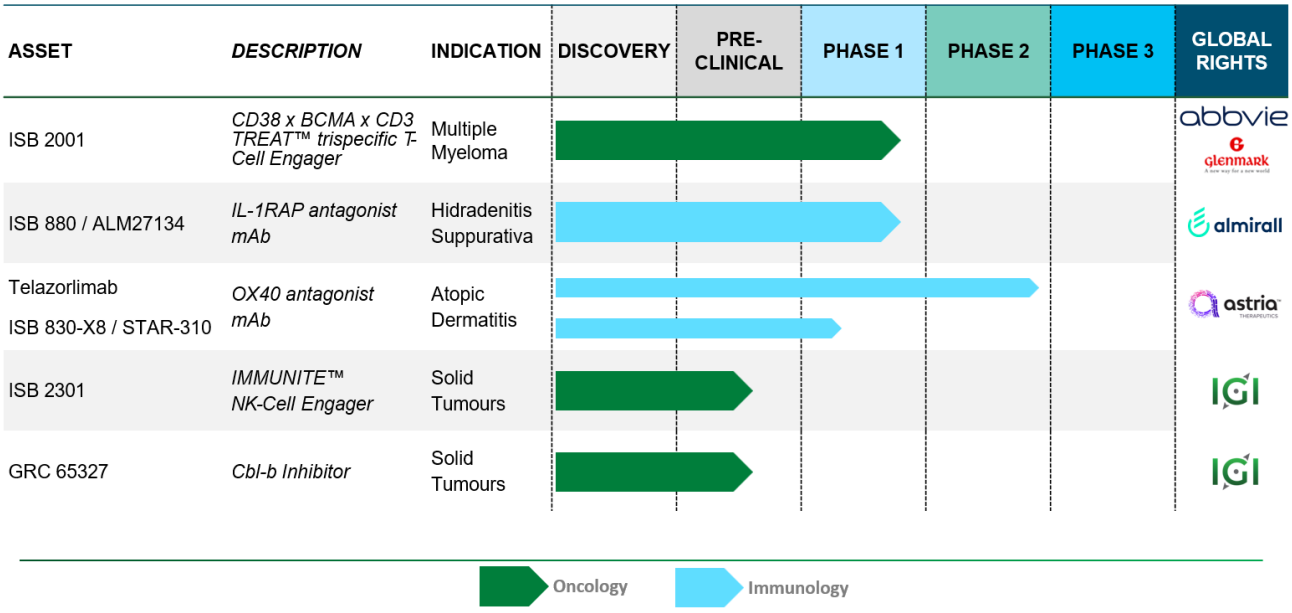
+ ISB 2001 Phase 1 study Part 2 (Dose Expansion) study initiated in Apr 2025 is enrolling rapidly

+ ISB 2001 EU CTA has been accepted by EU HA on 17 June 2025

+ ISB 2001 clinical abstract has been accepted at multiple conferences in H1 2025 and new clinical data has lately been presented in June 2025 at ASCO2025 in the Rapid Oral Abstract Session, followed by Poster Presentation at EHA2025 (encore) also in June 2025

+ During CY 2024-2025 IGI initiated a transitioning from in-house CMC manufacturing to a CDMO model to improve flexibility and scalability supporting the development of their assets from early to late phase development. The transition was fully completed by June 2025

Diversity of Immune Cell Engagement and Indications Across Hematologic and Solid Tumours



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. In June 2025, IGI received EU CTA acceptance to expand the trial in Europe (France, Italy, Spain, and Norway). The phase 1 TRIgnite-1 study is divided into a dose escalation (part 1) and a dose expansion (part 2), 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 start in Europe is targeted for end of Q3 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.

- At the **American Society of Hematology (ASH) Annual Meeting in December 2024**, IGI presented the first clinical results from its Phase I dose escalation TRIgnite-1 study:
  - **ORR: 83%** (n=18) at the therapeutic dose levels in a heavily pre-treated R/R MM population (median 6 prior lines of therapy, including CAR-Ts and bispecifics)[1]
  - **CR/sCR: 22%** (n=18) deep responses were seen across patients with or without prior BCMA targeted and/or T Cell Directed Therapies (bispecific and CAR-T)[1]
  - **Safety**; Mild CRS, No ICANS, well manageable neutropenia and infections, enabling continuation of study treatment[1]

- By **American Society of Clinical Oncology (ASCO) 2025**, expanded data from the TRIgnite-1 study dose escalation cohorts showed:
  - **ORR: 79%** (n=33) at the therapeutic dose levels in a heavily pre-treated R/R MM population (median 6 prior lines of therapy, including patient who failed prior CAR-Ts and bispecifics)[2]
  - **CR/sCR: 30%** (n=33), deep responses were seen across patients with or without prior BCMA targeted and/or T Cell Directed Therapies (bispecific and CAR-T)[2]
  - **Robust activity across key subgroups**: Effective regardless of prior CAR-T, TCEs, BCMA therapies, CD38-refractoriness, extramedullary disease, or high-risk cytogenetics, and ORR in subject with no prior CAR-T and/or TCE was 84%.[2]
  - **Durability of response**: Median DOR not reached at 9-month median follow-up[2]
  - **Safety**; Mild CRS, a single Grade 1 ICANS, well manageable neutropenia and infections, enabling continuation of study treatment[2]
  - **Pharmacokinetics:** Dose-proportional PK with a median half-life of 17 days supports less-frequent dosing[2]

[1] Quach H. et al., ASH2024, Oral Presentation
[2] Quach H. et al., ASCO2024, Oral Presentation

GRC 65327: 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. A third set of questions from DCGI SEC received on 4 June 2025 followed by face-to-face interaction on 15 July 2025. The amendment to protocol addressing questions is currently ongoing and it will be completed by 18 August 2025. A formal approval of NOC is awaited.

Overview of Immunology Candidates in Development

- 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. Almirall completed Phase I single and multiple ascending doses in healthy volunteers, presenting the results at the recent AAD meeting. The antibody showed a favorable safety and tolerability profile, along with a low immunogenicity risk, supporting further development for treating immune-mediated inflammatory skin disorders. A Phase II study in Hidradenitis Suppurativa is planned for late 2025.

- The second antibody, ISB 830 (telazorlimab) and its follow-on molecule ISB 830-X8 (STAR-0310), 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. ISB 830-X8 (STAR-0310) is in development for the treatment of AD and potentially other indications. Phase 1 trial was initiated in the first quarter of 2025.

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.	
	Other autoimmune diseases, including Rheumatoid Arthritis	U.S. IND for Rheumatoid Arthritis and other autoimmune indications is active.	
ISB 830-X8 (STAR-0310)	Atopic Dermatitis	Phase 1a	Next-generation version of ISB 830 with extended half-life and expected optimized affinity and safety profile. Phase 1 initiated in the first quarter of 2025.

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.

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 (STAR-0310) 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 phase 1a trial in healthy subjects started earlier this year and triggered the payment of a milestone to IGI in Q1 2025.

For more information on this asset, please visit astriatx.com