

### **Glenmark Pharmaceuticals Ltd.**

## **36<sup>th</sup> JP Morgan Healthcare Conference**

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### **Corporate Overview & Strategic Roadmap**

Ryaltris™ - GSP 301

**GBR 830** 

**GBR 1302** 



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# **Evolved into a successful global organization over** the last 17 years



	Year 2000		Year 2017
Wealth Creation	Revenue: <b>US\$ 31 mn</b> Market Cap.: <b>US\$ 40 mn</b>	<b>-</b>	Revenue: US\$ 1.4 bn  Market Cap: US\$ 2.5 bn
Manufacturing Footprint	2 formulations facilities	<b></b>	<ul><li>16 facilities across 4 continents;</li><li>7 approved by USFDA</li></ul>
International Operations	~8% of total revenues	<b></b>	>70% of total revenues Present in US, EU, RCIS, LATAM etc.
Innovation	Initiation of NME research	<b>=</b>	Novel molecules in pipeline Focused on Oncology, Dermatology and Respiratory
Employees	<1,000: Primarily in India	$\Rightarrow$	>13,000: Spread over 50 countries

# **Current business is spread across API, Branded and Generic Formulations**



#### **Formulations Development and Marketing**

**Branded Formulations** 

**Generics Formulations** 

API Manufacturing & Marketing

**NME & Specialty** 

Brand Building in Selected Therapies

**Substitution Model** 

Captive Consumption and External Sales

Biologics and Small Molecules

#### **Key geographies**

- India
- Russia & CIS
- Latin America
- Asia
- Africa
- CEE

#### **Key geographies**

- North America
- Western Europe

### **Key geographies**

- North America
- Europe
- Japan
- India
- Latin America

### **Key facilities**

- Switzerland
  - Dedicated center for biologics
- India
  - R&D center for NCEs
  - Development hub for specialty

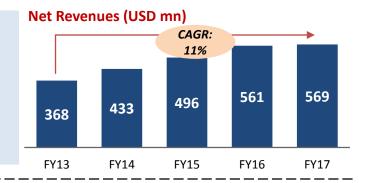
**Revenue generating segments** 

Investing for the future

### Robust growth exhibited across business segments

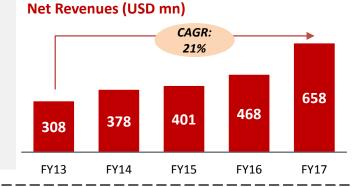
Branded Formulations

- CAGR of 11% over last five years
- Focused on brand building in select TAs
- Strong field force of 5,500+ globally



**Generic Formulations** 

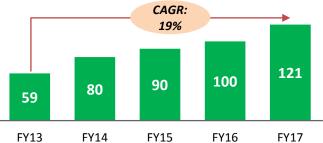
- CAGR of 21% over last five years
- Growth driven by niche products and selected large scale opportunities
- Leading Gx derma player in the US



**API** 

- CAGR of 19% over last five years
- Leadership position in multiple products
- Filed ~200 DMFs in various markets

### Net Revenues (USD mn)



# Roadmap to evolve into an innovative research led firm and launch proprietary products



- 2 major geographies US and India contributing ~60% of sales
- Generic formulation player in the US and WEU
- Branded formulation in other markets
- NME pipeline in early to mid stage of development
- Manufacturing base primarily in India

- US, India, Europe and API to contribute >80% of sales
- Increase presence in complex generics
- Launch specialty business in the US
- NME pipeline in advanced stage of development
- Expand manufacturing footprint

Medium term focus (next 3-5 years)

- Launch innovative and specialty products in multiple markets
- Significant revenues from specialty and innovation segments

Long term focus (next 5-10 years)

**Current position** 

# Focusing across the value chain in core therapy areas



Oncology

Dermatology

Respiratory

#### **Generics**

- Oncology injectables launched in EMs
- Oncology injectables under FDA approval
- Ranked #2 in India
- One of the leaders in the US Gx market – Launched 30+ products
- Launched inhalers in EMs
- g-Seretide approved in Nordic; filed in others
- Generic inhalers in development for US

### **Specialty/Complex Gx**

- Licensed g-Abraxane; FY19 filing
- Internally developing other complex generics
- Launched unique combinations in India, EMs
- Other innovative products in development
- 3 Specialty programs in pipeline for US – 1 in P3
- Unique combinations and devices in India, other EMs

#### **Innovative Products**

- Focused on bispecific and multivalent antibodies
- 2 bispecifics in Phase 1 in US and EU
- GBR 830 targeting Atopic
   Dermatitis in Phase 2b
- Other autoimmune disorders under evaluation
- Assets targeting respiratory disorders in late discovery stage
- Disease Areas: COPD, IPF



## **Overall NME and Specialty pipeline**

Therapy	Molecule	MoA/Class	Indication	Pre Clinical	Phase 1	Phase 2	Phase 3	Approval
Oncology	GBR 1302	HER2 X CD3	Breast Cancer Gastric Cancer					
Oncology	GBR 1342	CD38 X CD3	Multiple Myeloma					<b></b>
Oncology	GBR 1372	EGFR X CD3	Colorectal Cancer					
Dermatology	GBR 830	OX40 Antagonist	Atopic Dermatitis					
Respiratory	GRC 39815	Undisclosed	COPD, IPF					
Respiratory	Ryaltris™ - GSP 301	Steroid + AH	Allergic Rhinitis					
Respiratory	GSP 304	LAMA	COPD					
Respiratory	GBR 310	Biosimilar	Asthma, CIU					

#### Note:

- 1. Non-core assets include GRC 17536, GBR 900 and GBR 500. These 3 molecules and GRC 27864 are candidates for out-licensing
- 2. Ryaltris™ has been conditionally accepted as the brand name for GSP 301 Nasal Spray by the U.S. Food & Drug Administration (FDA)

# **Expected to file 9 NDA/BLA in the next decade across NME and Specialty portfolio**



Therapy Area	Molecule	Status	Filing Timelines (NDA/BLA)					
merapy raca			2018	2020	2022	2023 and Beyond		
Respiratory	Ryaltris™ - GSP 301	Phase 3	✓					
	GSP 304	Phase 2		✓				
	GBR 310	Phase 1		✓				
	GRC 39815	Pre Clinical				✓		
Dermatology	GBR 830	Phase 2			✓			
Oncology	GBR 1302	Phase 1			✓			
	GBR 1342	Phase 1				✓		
	GBR 1372	Pre Clinical				✓		



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**GBR 1302** 

### Ryaltris™ (GSP 301) – Nasal Spray

- Ryaltris™ is a fixed-dose combination (FDC) product in a nasal spray device
- Active components of Ryaltris™ Nasal Spray (NS)
  - Olopatadine hydrochloride (antihistamine)
  - Mometasone furoate (corticosteroid)
- Both of the individual components of the FDC are approved and marketed in various markets
  - Patanase® NS and Nasonex® NS in the United States (US)
  - Nasal Steroid Market opportunity
    - In Volume: ~55 mn units
    - In Value: ~USD 1.2 bn
  - Recent shift towards OTC yet the prescription market is significantly large

### Ryaltris™- Clinical Study Summary

- The clinical efficacy and safety of Ryaltris™ NS in Seasonal Allergic Rhinitis (SAR)
  was established in three placebo- and active-controlled, parallel-group
  comparative studies.
  - Ryaltris™ resulted in statistically significant and clinically relevant improvements on the primary efficacy measure (rTNSS)
  - Replicate evidence of the superiority of Ryaltris™ versus monotherapy components, as well as replicate evidence of the superiority of the individual monotherapies versus placebo, was established.
  - The safety profile of the Ryaltris™ fixed-dose combination therapy was comparable to placebo and each of its approved monotherapy constituents.
- Phase 3 study in Perennial Allergic Rhinitis (PAR) successfully completed with readout in Fall 2017
- Successful Pre-NDA meeting held targeting to file the NDA in H1 CY18

Ryaltris™ NS has the potential to offer patients a safe relief of the nasal symptoms of SAR in a single, convenient drug product that encourages greater patient compliance.



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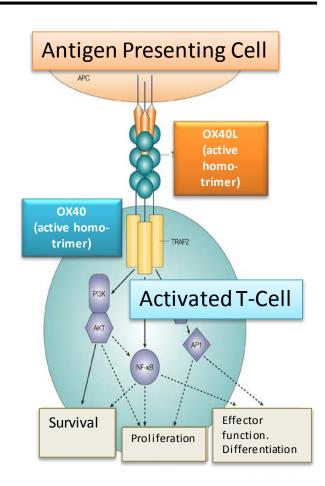
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### **GBR 830 – Asset Profile**

- GBR 830 is a humanized monoclonal antibody specific for OX40 (CD134)
- Novel MOA GBR 830 antagonizes the co-stimulatory molecule OX40 to reduce pathological immune responses
  - In many human autoimmune and inflammatory diseases
     OX40 and OX40L expression is increased at sites of inflammation and often correlated with disease severity
  - OX40 pathway blockade has beneficial therapeutic outcome in many autoimmune/inflammatory disease models: Arthritis, EAE, asthma/atopy, atherosclerosis, uveitis, transplant rejection, GvHD, colitis.
- Phase 2a clinical study has been completed in Atopic Dermatitis



First-in-Class and potentially Best-in-Class due to strong immune reduction focused on memory and chronic T-cell responses but sparing naïve T-cell function

### GBR 830 – Phase 2a Study Update

- Phase 2a, Double-Blind, Randomized, Placebo-controlled, Exploratory Multicenter
   Study of GBR 830 in Adult Patients with Moderate to Severe Atopic Dermatitis
- Purpose To explore safety and the clinical effect of GBR 830 on immune response biomarkers in patients with moderate to severe Atopic Dermatitis
- Primary Endpoints
  - Safety: Treatment-emergent adverse events and serious adverse events (SAEs)
  - Biologic Response: Effect of GBR 830 on lesioned mRNA expression and pathologic epidermal phenotype in skin biopsies of moderate-to-severe AD patients
  - Histology, Thickness, Immunohistology
- Secondary Endpoints
  - Clinical Efficacy: SCORAD, EASI 50, EASI 75 and IGA
  - Pharmacokinetics
- Exploratory Analysis

## GBR 830 – Phase 2a Results Summary and Conclusion



- GBR 830 was safe and well tolerated in moderate-to-severe AD patients
- 17 of 23 evaluable pts who completed the study had 50% reduction from baseline on EASI score (EASI 50) at 4 weeks after the 2nd dose
- Improvement in EASI score of GBR 830 treated patients was supported by change in SCORAD
- Most common treatment-related adverse event was headache, with no clinically meaningful differences between GBR 830 and placebo (4 percent and 6 percent, respectively).

Positive outcome of the 201 POC study met decision criteria to advance clinical development for GBR 830

- Initiation of a Phase 2b study in AD scheduled in H1 CY 2018
- Initiation of a Phase 2 exploratory study in SLE



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**GBR 830** 

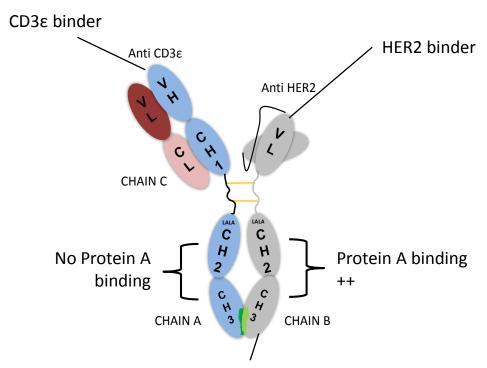
**GBR 1302** 

### **GBR 1302 Bispecific Antibody – Key Characteristics**

Proprietary technology platform (BEAT®) for developing novel bi-specific antibodies

– Tumor killing activity based on Redirected Lysis (RDL) of Tumor Cells by T cells

**GBR 1302: HER2 X CD3** 



#### Heterodimeric BEAT CH3 interface

#### **Key features of BEAT®**

- Efficiency in transferring tumor antigen binding scFv's into BEAT® format ("plug & play")
- Flexibility beyond CD3mediated engagement immunocytes
- Robustness and scalability of platform similar to standard mAb production

Programs such as GBR 1342 and GBR 1372 are based on similar structure and mechanism

### Why Target HER2?

- HER2 is a validated target but not fully exploited
- Restricted expression on normal tissue favors immunotherapy approach
- Several HER2+ tumors are non-responsive to approved anti-HER2 therapies
  - Breast, Bladder, Endometrial, Gastric
  - Several non-responders have TILs (Tumor infiltrated lymphocytes)
- HER2 is a validated target in gastric and gastroesophageal junction cancers are prime indications for CD3 engagers due to high levels of TILs

### **GBR 1302 – Clinical Update**

- Phase 1 Update
  - Dose escalation continues with clinical sites open in Europe and the U.S.
  - The study is currently recruiting HER2 positive patients in cohort 7.
  - Inclusion criteria: Progressive HER2 IHC-positive solid tumor with no available standard or curative treatment
- Primary Objectives: Maximum tolerated dose (MTD), Safety
- Secondary Objectives: Pharmacokinetics (PK) of single and repeated doses Immunogenicity. Anti-tumor activity, overall response rate (ORR), disease control rate (DCR), duration of response
- So far, 21 patients have been screened and 15 patients (including patients with gastric cancer, bladder cancer and breast cancer) have been dosed.
- In addition, GBR 1302 interim biomarker data and preclinical data is expected to be presented at medical meetings in CY 2018.



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**GSP 301** 

**GBR 830** 

**GBR 1302** 

### **Summary**

#### **Glenmark in 2017**

- 2 major geographies -US and India
- Revenue stream consisting of purely generics portfolio
- US, EU business based on substitution model
- NME pipeline in early to mid stages
- Manufacturing base primarily in India
- Profitability margin at ~20%

#### Glenmark in 2021

- US, India, Europe and API to contribute >80% of sales
- Increased presence in complex generics
- Scaling up the specialty business in the US
- NME pipeline in advanced stage of development
- Global manufacturing footprint
- Profitability margin at ~23%

#### Glenmark in 2025

- Launch of innovative products
- Specialty business ramp up in the US
- Specialty and Innovative segments to be the main growth drivers
- Increased presence in complex generics space
- Significant revenues from specialty and innovation segments
- Profitability margin at ~25%



## **THANK YOU**

