

## Management Discussion and Analysis for the First quarter of FY 2017 – 18

### **Revenue Figures – Consolidated**

#### (Rs. In Millions)

	First quarter ended June 30, 2017		
	FY 2017 – 18	FY 2016 – 17	Growth (%)
India	6,164.04	5,350.40	15.21%
US	10,450.29	6,981.85	49.68%
Rest of the World (ROW)	2,264.63	1,949.00	16.19%
Europe	1,620.78	1,499.52	8.09%
Latin America	845.11	1,556.23	-45.69%
ΑΡΙ	2,047.70	1,962.87	4.32%
Total	23,392.55	19,299.87	21.21%
Other Revenue	237.47	393.94	
Consolidated Revenue	23,630.02	19,693.81	19.99%

Average conversion rate in 3M FY 2017 – 18 considered as 64.38/USD 1.00

Average conversion rate in 3M FY 2016 – 17 considered as 66.83/ USD 1.00

USD figures are only indicative



## Review of Operations for the quarter ended June 30, 2017

For the first quarter ended June 30, 2017, Glenmark's consolidated revenue was at Rs. 23,630.02 Mn (USD 367.04 Mn) as against Rs. 19,693.81 Mn (USD 294.69 Mn) recording an increase of 19.99%.

## India

Sales for the formulation business in India for the first quarter ended June 30, 2017, was at Rs. 6,164.04 Mn (USD 95.74 Mn) as against Rs. 5,350.40 Mn (USD 80.06 Mn) in the previous corresponding quarter, recording a growth of 15.21%.

As per IMS MAT June 2017, Glenmark is ranked 14th compared to 16th in MAT June 2016 with a market share of 2.25% exhibiting value growth of 13.5% vis-à-vis industry growth of 8.2%.

Glenmark is among the top 3 fastest growing companies in India as per MAT June 2017. Presently Glenmark has 7 brands among the 'Top 300 Brands of the Indian Pharmaceutical Market.' The India business strengthened itself in the following therapeutic segments with growth in market share from IMS MAT June 2016 to MAT June 2017 respectively. The Cardiac segment market share increased from 3.9% to 4%; the Respiratory segment market share rose from 4.1% to 4.6%; the Anti-diabetic segment market share changed from 2.1% to 1.6%; and the Derma segment market share changed from 8.8% to 9.2%.

## **USA Formulations**

Glenmark Pharmaceuticals Inc., U.S.A. registered revenue from the sale of finished dosage formulations was Rs. 10,450.29 Mn (USD 162.32 Mn) for the quarter ended June 30, 2017 against revenue of Rs. 6,981.85 Mn (USD 104.47 Mn) for the previous corresponding quarter, recording an increase of 49.68%.

In the first quarter of fiscal year 2017-18, Glenmark was granted final approval and launched Atomoxetine Capsules USP, 10 mg, 18 mg, 25 mg, 40 mg, 60 mg, 80 mg and 100 mg, Fenofibrate Capsules USP [Micronized], 67 mg, 134 mg and 200 mg and Olmesartan Medoxomil Tablets, 5 mg, 20 mg and 40 mg. In addition, Glenmark was granted final approval of Indomethacin Extended-Release Capsules USP, 75 mg and Nebivolol Tablets, 2.5 mg, 5 mg, 10 mg and 20 mg. The Company filed two ANDA applications with the U.S. FDA, and plans to file an additional five applications in the forthcoming quarter.

Glenmark's marketing portfolio through June 30, 2017 consists of 118 generic products authorized for distribution in the U.S. market. The Company currently has 67 applications pending in various stages of the approval process with the US FDA, of which 27 are Paragraph IV applications.<sup>1</sup>

All brand names and trademarks are the property of their respective owners.



On Dec 12, 2016, Glenmark announced the availability of Ezetimibe, the first and only generic version of ZETIA<sup>®</sup> (Merck) in the United States for the treatment of high cholesterol. The availability of Ezetimibe is the result of a licensing partnership with Par Pharmaceutical, an Endo International plc operating company. Glenmark and its partner, Endo were entitled to 180 days of generic drug exclusivity for Ezetimibe as provided for under section 505(j)(5)(B)(iv) of the FD&C Act. The exclusivity period for the generic version of ZETIA<sup>®</sup> ended in early June 2017.

## Africa, Asia and CIS Region (ROW)

For the first quarter, revenue from Africa, Asia and CIS region was Rs. 2,264.63 Mn (USD 35.18 Mn) as against Rs. 1,949 Mn (USD 29.16 Mn) for the previous corresponding quarter, recording an increase of 16.19%.

As per IMS May 2017 data, Glenmark Russia recorded growth of 33.3% in value vis-à-vis overall market growth of 13.8%. In the Dermatology segment, Glenmark Russia grew by 39.6% vs the segment growth of 14.5%. According to IMS Health MAT May 2017, Glenmark Russia ranks 40 in the retail segment. For the first quarter, the Russia subsidiary grew 16% in constant currency.

The growth is attributed to the successful sales of Oflomil nail lacquer and the approval of its variation whereby the product may be used under nail varnish, which is an additional advantage. In the respiratory space, as per IMS MAT May 2017 Glenmark continues to secure a strong position and ranks 4<sup>th</sup> among the companies present in the expectorants market (retail segment).

During the first quarter, the Asia region recorded secondary sales growth of 6%. Glenmark launched two new products in the region – one in Malaysia and Myanmar each. The subsidiaries of Malaysia, Myanmar and Philippines registered a growth of 30%, 21 % and 5% respectively.

For the first quarter, the Africa subsidiary performed well. The two largest subsidiaries – Kenya and South Africa recorded good secondary sales growth during the quarter. Glenmark launched four new products during the quarter in the region.

## **Europe Formulations**

Glenmark Europe's operations revenue for the first quarter ended June 30, 2017 was at Rs. 1,620.78 Mn (USD 25.18 Mn) as against Rs. 1,499.52 Mn (USD 22.44 Mn) recording an increase of 8.09%.

For the first quarter FY 2018, Glenmark Europe recorded growth of over 25% in constant currency. Even though the region recorded good constant currency growth the overall performance of the European region was hampered year-on-year due to the currency depreciation of the British Pound. The Western European region recorded constant currency growth of 18%. During the

<sup>\*\*</sup>IMS Health National Prescription Audit: Retail Only [Extended Unit Total Prescriptions], May 2017



quarter the UK subsidiary launched 4 products while the German & Spain subsidiary launched 1 product each. The Central Eastern European region recorded good secondary sales growth for the first quarter. The Czech and the Slovak subsidiary launched 5 products each during the quarter.

## Latin America

Glenmark's revenue from its Latin American and Caribbean operations was at Rs. 845.11 Mn (USD 13.13 Mn) for the first quarter ended June 30, 2017 as against Rs. 1,556.23 Mn (USD 23.29 Mn), recording decrease of 45.69%.

The sharp decline for the Latin American region is on account of sales from the Venezuela subsidiary recorded in the previous corresponding quarter. Excluding Venezuela the region grew in excess of 15% in constant currency. The Mexico subsidiary recorded strong growth in excess of 60% in constant currency.

### Active Pharmaceutical Ingredients (API)

Revenue from sale of API to regulated and semi-regulated markets globally was Rs. 2,047.70 Mn (USD 31.81 Mn), for the quarter ended June 30, 2017 against Rs. 1,962.87 Mn (USD 29.37 Mn) for the previous corresponding quarter, recording an increase of 4.32%.

During the quarter, Glenmark filed one DMF in US, one Canada and one in Europe. The sales trajectory continued to remain good on account of sales from Olmesartan & Lercanidipine. Glenmark also launched Etoricoxib with partners in Europe.

## **Research & Development**

The company has a pipeline of 7 new molecular entities (NMEs), which includes 2 new chemical entities (NCEs) and 5 new biological entities (NBEs), in various stages of clinical development focused in the therapeutic areas of oncology, respiratory and dermatology. The company also has 3 specialty products in clinical development targeting key indications in the respiratory therapy area.

Glenmark's research centers are based in Navi Mumbai, India and Neuchâtel, Switzerland. Spread over 125,000 square feet the R&D center in India has end-to-end capabilities for discovery and development of NCEs from target selection to clinical development. The research facility is equipped with state-of-the-art infrastructure required to carry out research activities like medicinal chemistry, process and analytical chemistry, in vitro and in vivo studies and project management. Glenmark's dedicated R&D center for biologics in Switzerland has end-to-end capabilities to discover NBE's and to support clinical development. It is also fully equipped to manufacture and supply clinical trial material.

#### **BEAT®** Technology



BEAT<sup>®</sup> (Bispecific Engagement by Antibodies based on the T cell receptor) is Glenmark's proprietary technology for the production of bispecific antibodies (bsAbs), leading to engagement and activation of naturally occurring T cells when bridging to tumor cells. With BEAT<sup>®</sup> technology, Glenmark's scientists have been able to overcome past production obstacles encountered with bsAbs and efficiently manufacture these molecules on an industrial scale. Preclinically, BEAT<sup>®</sup> bsAbs demonstrate the potential for more potent activity compared to existing therapeutic antibodies. Additionally, structural similarity to naturally-occurring antibodies may result in a normalized IgG half-life and less immunogenicity.

### **ONCOLOGY ASSETS**

#### GBR 1302

GBR 1302, a HER2xCD3 bsAb, is the first clinical candidate based on Glenmark's proprietary BEAT<sup>®</sup> platform. Preclinical study results from redirected lysis assays suggest GBR 1302, in comparison to current 1st and 2nd line HER2-targeted monoclonal antibodies, exhibits faster and more complete killing of HER2+ tumor cells. If confirmed in clinical trials, GBR 1302 will constitute an innovative treatment for HER2 positive cancers, including treatment-resistant cancers. A Phase 1 study is underway to determine maximum tolerated dose (MTD). Dosing escalation is continuing.

#### GBR 1342

GBR 1342, a CD38xCD3 bsAb based on Glenmark's proprietary BEAT<sup>®</sup> platform targets CD38, a clinically proven target in multiple myeloma. Results from preclinical assays in comparison to daratumumab, an FDA-approved monoclonal antibody targeting CD38, suggest that GBR 1342 has a potent antitumor effect on patient derived multiple myeloma cell lines. GBR 1342 is targeting multiple myeloma and other malignancies of hematopoietic origin. Glenmark received clearance from the FDA on an Investigational New Drug Application (IND) for GBR 1342 in May 2017 and plans to initiate the study in the Q2-Q3 of this financial year.

New treatments have improved the survival rate in multiple myeloma patients, but the disease remains incurable. Based on the most recent data, globally there are more than 100,000 new cases of multiple myeloma diagnosed every year.

#### GBR 1372

GBR 1372 is an EGFRxCD3 bsAb based on Glenmark's proprietary BEAT<sup>®</sup> platform. It targets epidermal growth factor receptor, a proven target in several cancers including squamous cell carcinoma of the head and neck and colorectal cancer. GBR 1372 has demonstrated the ability to bypass KRAS and BRAF mutation limitations of current therapies such as Erbitux/Vectibix in preclinical studies. It is currently being evaluated for the treatment of colorectal cancer, refractory to Erbitux/Vectibix. GBR 1372 is currently in preclinical development and is also being evaluated as a potential treatment for non-small cell lung cancer and head and neck cancers.



Based on the most recent data, colorectal cancer is the fourth leading cause of cancer death worldwide. KRAS mutations occur in 35-45% of colorectal cancer cases, patients with these mutations will not respond to or do not benefit from traditional EGRF-inhibiting therapies.

#### GBR 8383

GBR 8383 is a new type of highly potent OX40R antibody based agonist in preclinical studies. OX40R is an immuno-oncology target and member of the TNFR superfamily. It is expressed on activated CD4 and CD8 T cells as well as a number of other lymphoid and non-lymphoid cells. Preclinical data has confirmed a strong agonistic effect on the immuno-oncology target OX40R in comparison to other OX40 agonists currently in the clinic.

Generating optimal T cell responses through co-stimulation of TNFR superfamily members like OX40 may lead to enhanced activity against a variety of tumors.

### DERMATOLOGY ASSET

#### GBR 830

GBR 830, an anti-OX40R monoclonal antibody, was discovered at the Glenmark Biologics Research Centre located in Switzerland and is in clinical development by Glenmark USA. The molecular target of GBR 830 is to inhibit pathologically activated T cells and effector memory T cells which are involved in a variety of autoimmune and chronic inflammatory disorders. The lead indication being evaluated for GBR 830 is moderate-to-severe atopic dermatitis. GBR 830 has been investigated in Phase 1 studies with healthy volunteers and was safe and well tolerated with no significant safety issues. GBR 830 is currently in a Phase 2 proof of concept study in the U.S. and Canada in adults suffering from moderate-to-severe atopic dermatitis. Initial data readout from the Phase 2 study is expected in the second half of CY 2017. Glenmark is targeting a BLA filing for GBR 830 in 2022. Evaluation of GBR 830 for the treatment of other autoimmune disorders is also underway.

Atopic dermatitis is the most common inflammatory skin disease, affecting up to 3% of the adult population and its prevalence has increased 2-3 fold over the last 100 years. Biologic agents in moderate-to-severe atopic dermatitis offer promise to both control the disease and prevent the occurrence of new skin lesions.

#### **RESPIRATORY ASSETS**

#### GRC 39815

GRC 39815 is a NCE currently in preclinical studies. It is being evaluated as an inhaled compound for the possible treatment of Chronic Obstructive Pulmonary Disorder (COPD). It is an inhibitor of



the Retinoid-related Orphan Receptor gamma t (ROR  $\gamma$  t). Preclinical studies suggest efficacy in animal models supporting respiratory indications.

## GSP 301

GSP 301 is a combination of a steroid and an anti-histamine administered intranasally for the treatment of seasonal allergic rhinitis in adults and children. Glenmark reported positive results from a Phase 3 trial where GSP 301 demonstrated statistically significant and clinically meaningful improvement from baseline for the primary endpoint of average morning and evening patient-reported reflective Total Nasal Symptom Score, compared to placebo (p <0.001), oloapatadine (p=0.028) and mometasone (p=0.019). All investigational treatments administered in the trial were well-tolerated, and showed no meaningful differences in reported adverse events (AEs) across treatments. The most common AE occurring in at least two percent of patients was dysgeusia.

Glenmark recently received confirmation from the FDA that the data from this Phase 3 trial is sufficient and no further studies are needed to support a New Drug Application (NDA) filing for GSP 301. Glenmark plans to submit a 505(b)(2) NDA in early CY 2018.

According to the most recent data, over 17 million adults and 6 million children in the U.S. are affected by seasonal allergic rhinitis, also called hay fever, every year. Currently, there is only one product available in the U.S. that combines a steroid and antihistamine in a single spray. This limits treatment options for people with hay fever and can increase the cost and complexity of treatment.

#### GSP 304

GSP 304 is a long-acting muscarinic antagonist for administration by nebulization for the long term, once-daily, maintenance treatment of bronchospasm associated with COPD. Glenmark has initiated a Phase 2 study for patients with mild to moderate COPD as established by the Global Initiative for Chronic Obstructive Lung Disease.

Based on the most recent estimates COPD affects approximately 64 million people worldwide. COPD is an incurable disease and based on the most recent data is the third leading cause of death worldwide.

#### GBR 310

GBR 310 is a biosimilar candidate being developed for the treatment of asthma and chronic idiopathic urticaria. Glenmark has initiated a Phase 1 study which will assess the pharmacokinetics of GBR 310 in comparison to the reference product. GBR 310 has the potential to be among the



first biosimilar candidates to be submitted for approval for a respiratory or allergic disease in the U.S.

Asthma affects an estimated 300 million people worldwide and the morbidity and economic burden is significant, with approximately 240,000 asthma-related deaths per year. Chronic idiopathic urticaria is a common skin disease that presents as spontaneously occurring hives or welts. It occurs across all age groups and about one percent of the population suffers from a chronic form of the disease.

#### PAIN ASSET

#### GRC 27864

GRC 27864 is a potent, selective, and orally bioavailable inhibitor of microsomal prostaglandin E synthase-1 (mPGES-1), a novel therapeutic target in pain management, which is upregulated under inflammatory conditions. A Phase 1 single ascending dose and a multiple ascending dose study have been completed in the UK with no safety concerns. It is currently in Phase 2 development. The most common AEs for patients receiving single doses were headaches and dizziness. For patients who received multiple doses the most common AEs were nausea, diarrhea and abdominal pain, none of which were dose limiting.

Non-core assets include GRC 17536, GBR 900 and GBR 500. These 3 molecules and GRC 27864 are candidates for out-licensing.

#### Disclaimer

This document has been prepared by Glenmark Pharmaceuticals Ltd. The information, statements and analysis made in this document describing company's objectives, projections and estimates are forward looking statements and progressive within the meaning of applicable Security Laws and Regulations. The analysis contained herein is based on numerous assumptions. Actual results may vary from those expressed or implied depending upon economic conditions, government policies and other incidental factors. No representation or warranty, either expressed or implied, is provided in relation to this presentation. This presentation should not be regarded by recipients as a substitute for the exercise of their own judgment.