

## Management Discussion and Analysis for the Third quarter of FY 2016 – 17

**Revenue Figures – Consolidated** 

(Rs. In Millions)

	Third quarter ended December 31			Nine months ended December 31		
	FY 2016 – 17	FY 2015 – 16	Growth (%)	FY 2016 – 17	FY 2015 – 16	Growth (%)
India	5,168.74	4,880.30	5.91 %	17,268.45	15,695.02	10.02 %
US	12,308.26	6,088.68	102.15 %	27,002.17	17,683.41	52.70 %
Rest of the World (ROW)	2,511.00	2,363.39	6.25 %	6,998.49	6,052.12	15.64 %
Europe	1,957.09	1,763.53	10.98 %	4,803.55	4,465.56	7.57 %
Latin America	947.20	1,237.26	(23.44) %	3,841.35	5,078.73	(24.36) %
ΑΡΙ	1,920.52	1,449.80	32.47 %	6,096.81	4,454.23	36.88 %
Total	24,812.81	17,782.96	39.53 %	66,010.82	53,429.07	23.55 %
Other Revenue	537.27			1274.16		
Consolidated Revenue	25,350.08	17,782.96	42.55 %	67,284.98	53429.07	25.93 %

Average conversion rate in Q3 FY 2016 – 17 considered is 66.99/USD 1.00

Average conversion rate in Q3 FY 2015 – 16 considered is 64.64/ USD 1.00

USD figures are only indicative



## Review of Operations for the quarter ended December 31, 2016

For the third quarter ended December 31, 2016, Glenmark's consolidated revenue was at Rs. 25,350.08 Mn (USD 377.11 Mn) as against Rs. 17,782.96 Mn (USD 270.15 Mn) recording an increase of 42.55%. Glenmark's consolidated revenue excluding other revenue was at Rs. 24,812.81 Mn (USD 369.11 Mn) as against Rs. 17,782.96 Mn (USD 270.15 Mn) recording an increase of 39.53%

For the nine months ended December 31, 2016, Glenmark's consolidated revenue was at Rs. 67,284.98 Mn (USD 1,004.41 Mn) as against Rs.53,429.07 Mn (USD 826.50 Mn) recording an increase of 25.93%. Glenmark's consolidated revenue excluding other revenue was at Rs. 66,010.82 Mn (USD 985.39 Mn) as against Rs. 53,429.07 Mn (USD 826.50 Mn) recording an increase of 23.55 %.

#### India

Sales for the formulation business in India for the third quarter ended December 31, 2016, was at Rs. 5,168.74 Mn (USD 76.78 Mn) as against Rs. 4,880.30 Mn (USD 73.99 Mn) in the previous corresponding quarter, recording growth of 5.91 %.

As per IMS MAT December 2016, Glenmark improved its ranking to 15<sup>th</sup> compared to 17<sup>th</sup> as on MAT December 2015 with increase in market share by 0.1%, exhibiting a value growth of 15% vis-à-vis IMP growth of 10%. Glenmark presently has 8 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 December 2016 to MAT December 2015 respectively. The Cardiac segment market share increased from 3.80% to 4%; the Respiratory segment market share rose from 4% to 4.4%; the Anti-diabetic segment market share changed from 2. 3% to 1.80%; and the Derma segment market share rose from 8.4% to 9.1%.

#### **USA Formulations**

Glenmark Pharmaceuticals Inc., U.S.A. registered revenue from the sale of finished dosage formulations was at Rs. 12,308.26 Mn (USD 183.27 Mn) for the quarter ended December 31, 2016 against revenue of Rs. 6,088.68 Mn (USD 92.58 Mn) for the previous corresponding quarter, recording an increase of 102.15 %.

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 will be 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

In the third quarter of fiscal year 2016-17, Glenmark was granted final approval and launched Nystatin and Triamcinolone Acetonide Cream USP; and launched Triamcinolone Acetonide Cream USP, 0.1% and Potassium Chloride Extended-Release Tablets USP, 10 mEq & 20 mEq. The company filed five ANDA applications with the U.S. FDA, and plans to file an additional 10 applications in the forthcoming quarter. The total number of ANDAs filed during this year was eleven.

Glenmark's marketing portfolio through December 31, 2016 consists of 112 generic products authorized for distribution in the U.S. market. The Company currently has 63 applications pending in various stages of the approval process with the US FDA, of which 24 are Paragraph IV applications.

## Africa, Asia and CIS Region (ROW)

For the third quarter, revenue from Africa, Asia and CIS region was Rs. 2,511.00 Mn (USD 37.34 Mn.) as against Rs. 2363.39 Mn (USD 36.05 Mn) for the previous corresponding quarter, recording in an increase 6.25%.

In the third quarter of the fiscal year 2016-17, the secondary sales for the Russian subsidiary recorded growth of 34% (vs same period last year) and YTD Dec'16 growth was at 44% (vs same period last year). According to IMS Health MAT November'16 data, Glenmark Russia's dermatology business grew by 65.1 % v/s overall dermatology growth of 9.9 %. The overall growth for the dermatology business is still driven from the strong growth in Oflomil nail lacquer and Klenzit C.

The Asia and the Africa business recorded an average performance during the quarter. The subsidiaries of Malaysia, Vietnam and South Africa recorded good secondary sales growth for the third quarter. During the quarter Glenmark launched 2 products in the Asia region and 5 products in the Africa region.

#### **Europe Formulations**

Glenmark Europe's operations revenue for the third quarter ended December 31, 2016 was at Rs. 1,957.09 Mn (USD 29.13 Mn) as against Rs. 1,763.53 Mn (USD 26.91 Mn) recording increase of 10.98%.

For the third quarter of the financial year, Glenmark Europe business grew by 15 % on a constant currency aided by good growth in the Western Europe region. The UK subsidiary performed well in the third quarter. The Central Eastern Europe region continued to remain subdued thus



impacting the overall growth for the region. During the quarter, four products were launched in the UK, four product were launched in Germany and two products launched in Spain



## Latin America

Glenmark's revenue from its Latin American and Caribbean operations was at Rs. 947.20 Mn (USD 14.05 Mn) for the third quarter ended December 31, 2016 as against Rs. 1237.26 Mn (USD 18.61 Mn), recording decrease of 23.44 %.

The latam region continued to remain subdued on account of the base effect from sales arising from Venezuela. The overall growth for the Brazilian subsidiary in the third quarter continues to be impacted due to the weak economic environment and due to lack of new product approvals. The Mexico subsidiary recorded double digit growth in constant currency for the quarter.

## **Active Pharmaceutical Ingredients (API)**

Revenue from sale of API to regulated and semi-regulated markets globally was Rs. 1,920.52 Mn (USD 28.54 Mn), for the quarter ended December 31, 2016 against Rs. 1,449.80 Mn (USD 22.01 Mn) for the previous corresponding quarter, recording an increase of 32.47 %.

Glenmark filed for two US DMF during the quarter. The good growth of the business was due to the successful launch of Olmesartan with Mylan under 180 days market exclusivity. The good growth was contributed by sale of Perindopril, Adapalene, Amiodarone.

#### **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 disease and dermatology. The company also has 3 specialty products in clinical development targeting the key indications in the respiratory therapy area.

Glenmark's research centers for NMEs are headquartered in Navi Mumbai, India and Neuchâtel, Switzerland. Spread over 1,25,000 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 and develop NBEs and for preclinical studies. It is also fully equipped to manufacture clinical trial size batch materials.

### **BEAT®** Technology

BEAT<sup>®</sup> (Bispecific Engagement by Antibodies based on the T cell receptor) is Glenmark's proprietary technology for the production of bi-specific antibodies (bsAbs). Engaging two targets with one bispecific antibody is an approach to target cancer cells, for instance by the redirection of cytolitic T cells. With the 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.

#### **ONCOLOGY ASSETS**

#### GBR 1302

GBR 1302, a HER2xCD3 bispecific antibody, is the first clinical candidate based on Glenmark's proprietary best-in-class BEAT<sup>®</sup> platform. Preclinical study results from redirected lysis assays suggest GBR 1302 has superiority to current 1<sup>st</sup> and 2<sup>nd</sup> line HER2-targeted monoclonal antibodies through 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, and potentially prove superior to the currently available monoclonal antibody treatments. Glenmark has initiated a Phase 1 trial for GBR 1302 in Germany and will soon expand recruitment to the USA.

#### GBR 1342

GBR 1342, a CD38xCD3 bispecific antibody based on Glenmark's proprietary BEAT<sup>®</sup> platform. It targets CD38, a 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 more potent antitumor effect on patient derived multiple myeloma cell lines. GBR 1342 is also being developed for the treatment of other malignancies of hematopoietic origin. Glenmark plans to file an Investigational New Drug (IND) application to initiate a Phase 1 study in the second half of CY 2017.

New treatments have improved the survival rate in multiple myeloma patients, but the disease remains incurable. Given the age of the patient population there are also substantial challenges in managing the toxicity of available therapies.

#### GBR 8383

GBR 8383 is a new type of highly potent OX40R agonist and it potentially represents the first in a new class of potent Immuno-Oncology molecules. OX40R is a member of the TNFR superfamily and 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 targetOX40R in comparison to other OX40 agonists currently in the clinic.

#### GBR 1372

GBR 1372 is an EGFRxCD3 bispecific antibody 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. *In vivo* preclinically GBR 1372 has demonstrated preclinically the ability to bypass KRAS and BRAF mutation limitations of current therapies such as Erbitux/Vectibix. It is currently being developed for the treatment of colorectal cancer refractory to Erbitux/Vectibix. GBR 1372 is currently in pre-clinical studies and is also being developed for non-small cell lung cancer (NSCLC) and Head & Neck cancers.



Based on the most recent data, colorectal cancer is the fourth leading cause of cancer death worldwide. Currently, the most reliable way to predict whether a colorectal cancer patient will respond to EGFR-inhibiting drugs is to test for certain mutations in the gene that encodes KRAS, which occurs in 35%-45% of colorectal cancers.

### DERMATOLOGY ASSET

#### GBR 830

GBR 830, an anti-OX40R monoclonal antibody, was discovered at the Glenmark Biologics Research Centre located in Switzerland. It is a OX40R antagonist targeting activated T cells and effector memory T cells. In a Phase 1 study GBR 830 was safe and well-tolerated with no significant safety issues. GBR 830 is currently in an ongoing Phase 2 proof of concept study in the U.S.A. and Canada in adults suffering from moderate-to-severe atopic dermatitis. Development 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 388XX**

GRC 388XX is a NCE currently in pre-clinical studies. Targeted indications for GRC 388XX included chronic obstructive pulmonary disorder (COPD) and idiopathic pulmonary fibrosis (IPF). Its class and mechanism of action are currently undisclosed.

#### GSP 301

GSP 301 is a specialty combination of a steroid and an anti-histamine administered intranasally for the treatment of seasonal allergic rhinitis in adults and children. Glenmark has two ongoing Phase 3 trials to support its regulatory review. Despite advances in therapy there is increasing prevalence of allergic rhinitis in countries with a Western lifestyle. Although topical nasal corticosteroids and non-sedating antihistamines are highly effective in treating allergic rhinitis, there remains a group of patients who have a poor response to these treatments.

#### 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 plans to initiate a Phase 2 study in the next six months for patients with mild to moderate COPD as established by the Global Initiative for Chronic Obstructive Lung Disease.



COPD is a preventable, but 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 currently in preclinical studies being developed for the treatment of asthma and chronic idiopathic urticaria. GBR 310 has the potential to be among the first respiratory biosimilars approved in the USA.

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.

#### GRC 27864

GRC 27864 is a candidate for out-licensing. It 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 up-regulated under inflammatory conditions. A Phase I first-in-human single ascending dose and a multiple ascending dose study has been completed in the UK with no safety concerns. It is currently in Phase 2 development.

The rest of the assets such as GRC 17536, GBR 900, GBR 500 continue to progress. These 3 molecules and GRC 27864 are candidates for out-licensing.

#### Disclaimer

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