

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

# **Revenue Figures - Consolidated**

(Rs. In Millions)

	Fourth quarter ended March 31			Twelve months ended March 31		
	FY 2016 – 17	FY 2015 – 16	Growth (%)	FY 2016 – 17	FY 2015 – 16	Growth (%)
India	5,769.32	5,397.72	6.88%	23,037.77	21,092.74	9.22%
US	10,004.46	6,519.78	53.45%	37,006.63	24,203.20	52.90%
Rest of the World (ROW)	2,889.37	2,980.42	-3.06%	9,887.86	9,032.54	9.47%
Europe	2,297.80	2,705.10	-15.06%	7,101.35	7,170.66	-0.97%
Latin America	1,339.88	2,416.33	-44.55%	5,181.22	7,495.06	-30.87%
АРІ	1,997.24	2,228.66	-10.38%	8,094.10	6,682.88	21.12%
Total	24,298.07	22,248.01	9.21%	90,308.93	75,677.08	19.33%
Other Revenue	273.76	818.75		1,547.88	818.75	
Consolidated Revenue	24,571.83	23,066.76	6.52%	91,856.81	76,495.83	20.08%

Average conversion rate in 12M FY 2016 - 17 considered as 66.97/USD 1.00 Average conversion rate in 12M FY 2015 - 16 considered as 65.32/ USD 1.00 USD figures are only indicative



# Review of Operations for the quarter ended March 31, 2017

For the fourth quarter ended March 31, 2017, Glenmark's consolidated revenue was at Rs. 24,571.83 Mn (USD 367.20 Mn) as against Rs. 23,066.76 Mn (USD 344.51 Mn) recording an increase of 6.52%.

For the twelve months ended March 31, 2017, Glenmark's consolidated revenue was at Rs. 91,856.81 Mn (USD 1,371.62 Mn) as against Rs. 76,495.83 Mn (USD 1,171.02 Mn) recording an increase of 20.08%.

#### India

Sales for the formulation business in India for the fourth quarter ended March 31, 2017, was at Rs. 5,769.32 Mn (USD 86.22 Mn) as against Rs. 5,397.72 Mn (USD 80.11 Mn) in the previous corresponding quarter, recording a growth of 6.88%.

As per IMS MAT March 2017, Glenmark improved its rank to 15<sup>th</sup> compared to 18<sup>th</sup> as of MAT March 2016 with increase in market share by 0.2%, exhibiting value growth of 14% vis-à-vis IPM growth of 9%. 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 March 2017 to MAT March 2016 respectively. The Cardiac segment market share increased from 3.9% to 4%; the Respiratory segment market share rose from 4.1% to 4.5%; the Anti-diabetic segment market share changed from 2.2% to 1.70%; and the Derma segment market share changed from 8.6% to 9.2%.

#### **USA Formulations**

Glenmark Pharmaceuticals Inc., U.S.A. registered revenue from the sale of finished dosage formulations was Rs. 10,004.46 Mn (USD 149.51 Mn) for the quarter ended March 31, 2017 against revenue of Rs. 6,519.78 Mn (USD 96.96 Mn) for the previous corresponding quarter, recording an increase of 53.45%.

On Dec 12, 2016, Glenmark announced the availability of Ezetimibe, the first and only generic version of ZETIA® (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. The exclusivity period continued during the entire fourth quarter.

In the fourth quarter of fiscal year 2016-17, Glenmark was granted final approval and launched Clobetasol Propionate Ointment USP, 0.05%, the generic version of Temovate® Ointment, 0.05% of Fougera Pharmaceuticals Inc.; and launched Tretinoin Capsules, 10 mg, Glenmark's first and



only soft-gelatin capsule. In the fourth quarter, Glenmark filed nine ANDA's with the U.S. FDA, and plans to file three applications in the forthcoming quarter.

During the year, Glenmark filed 20 ANDA applications with the U.S. FDA. Out of these, 9 were dermatological products, 3 were hormonal products, 1 was onco injectable and 7 applications were oral solids out of which majority were complex or niche products.

In the fiscal year 2016-17, Glenmark was granted approval of 17 Abbreviated New Drug Applications (ANDA), comprising of 11 final approvals and 6 tentative approvals. Notable approvals include: Rosuvastatin Calcium Tablets; Diclofenac Sodium Gel, 3%, and Lidocaine Ointment USP, 5%.

Glenmark's marketing portfolio through March 31, 2017 consists of 113 generic products authorized for distribution in the U.S. market. The Company currently has 65 applications pending in various stages of the approval process with the U.S. FDA, of which 25 are Paragraph IV applications.

During the last four months, Glenmark's Goa and Baddi manufacturing facility was inspected by the U.S. FDA. The Baddi manufacturing facility at Himachal Pradesh did not receive any observations. The Goa manufacturing facility received 4 observations to which we have responded to the U.S. FDA. At this point in time, we do not have any outstanding items with the U.S. FDA regarding these plants.

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

\*\*IMS Health National Sales Perspectives: Retail and Non-Retail, February 2017

## Africa, Asia and CIS Region (ROW)

For the fourth quarter, revenue from Africa, Asia and CIS region was Rs. 2,889.37 Mn (USD 43.18 Mn) as against Rs. 2,980.42 Mn (USD 44.65 Mn) for the previous corresponding quarter, recording a decrease of 3.06%.

In the fourth quarter of the financial year 2016-17, the Russian subsidiary recorded moderate secondary sales growth vis-à-vis the same period last year with YTD March 2017 secondary sales growth of 33% (vs same period last year). According to IMS Health MAT February 2017 data, Glenmark Russia ranks 42 which sustains Glenmark's position among the list of TOP-45 companies in the retail segment of the Russian pharmaceutical market. During the quarter, Glenmark launched Momat Rino (nasal spray) in the Russia market.

For the fourth quarter, the Asia region recorded a below average performance. The Africa region's performance was also average and Glenmark launched three new products during the quarter in the region. The subsidiaries of South Africa and Kenya recorded good secondary sales growth during the quarter.



## **Europe Formulations**

Glenmark Europe's operations revenue for the fourth quarter ended March 31, 2017 was at Rs. 2,297.80 Mn (USD 34.33 Mn) as against Rs. 2,705.10 Mn (USD 40.69 Mn) recording a decrease of 15.06%. The growth was impacted due to the currency depreciation of the British Pound.

For the fourth quarter of the financial year, the Europe region performance has been mixed. While the Western European region recorded good growth in constant currency during the quarter, the Eastern European region recorded a decline in sales. The growth in Western Europe was aided by the good performance of the UK and the German subsidiaries. In the fourth quarter, there were few product launches in the UK, Germany, Spain, and the Poland region. For the entire financial year, the region launched nearly 25 products across markets and in licensed over 35 products.

#### **Latin America**

Glenmark's revenue from its Latin American and Caribbean operations was at Rs. 1,339.88 Mn (USD 20.02 Mn) for the fourth quarter ended March 31, 2017 as against Rs. 2,416.33 Mn (USD 36.17 Mn), recording decrease of 44.55%.

The Latam region performance continues to be impacted on account of the sales from Venezuela in the fourth quarter of the previous year. While the Mexico subsidiary recorded good sales growth, the Brazil subsidiary performance was average.

# **Active Pharmaceutical Ingredients (API)**

Revenue from sale of API to regulated and semi-regulated markets globally was Rs. 1,997.24 Mn (USD 29.85 Mn), for the quarter ended March 31, 2017 against Rs. 2,228.66 Mn (USD 33.40 Mn) for the previous corresponding quarter, recording a decrease of 10.38%.

During the quarter, Glenmark filed three US DMF, one Canada and one in Europe. Glenmark also received an EIR from the U.S. FDA for its Ankleshwar facility.

## **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 headquartered 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 and develop NBEs and for preclinical studies. It is also fully equipped to manufacture and supply clinical trial material.

# **BEAT® Technology**

BEAT® (Bispecific Engagement by Antibodies based on the T cell receptor) is Glenmark's proprietary technology for the production of bispecific antibodies (bsAbs). Engaging two targets with one bsAb is an approach to target cancer cells, for instance by the redirection of cytolytic T cells. With the BEAT® 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 bsAb, is the first clinical candidate based on Glenmark's proprietary BEAT® platform. Preclinical study results from redirected lysis assays suggest GBR 1302, in comparison to current 1<sup>st</sup> and 2<sup>nd</sup> 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 resistant cancers.

#### **GBR 1342**

GBR 1342, a CD38xCD3 bsAb based on Glenmark's proprietary BEAT® 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 plans to file an Investigational New Drug (IND) application to initiate a Phase 1 study in the first half of CY 2017.

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® 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 developed for the treatment of colorectal cancer, refractory to Erbitux/Vectibix. GBR 1372 is currently in preclinical studies and is also being developed for non-small cell lung cancer and head & 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. 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 target OX40R in comparison to other OX40 agonists currently in the clinic.

# **DERMATOLOGY ASSET**

#### **GBR 830**

GBR 830, an anti-OX40R monoclonal antibody, was discovered at the Glenmark Biologics Research Centre located in Switzerland. It is an 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 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. 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 39815**

GRC 39815 is a NCE currently in IND-enabling toxicology studies. It is being developed as an inhaled compound for treatment of Chronic Obstructive Pulmonary Disorder (COPD). It is an inhibitor of the Retinoid-related Orphan Receptor gamma t (ROR  $\gamma$  t) thereby inhibiting the release of inflammatory cytokines reported to be involved in the pathogenesis of COPD. GRC 39815 has demonstrated effective lung retention following drug delivery.



## **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 recently 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 plans to meet with the FDA to discuss the 505(b)(2) New Drug Application (NDA) filing strategy for GSP 301 in the second half of CY 2017.

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.

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. Glenmark is targeting a 351(k) BLA filing in 2020. 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. 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.



## **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, GBR 500. These 3 molecules and GRC 27864 are candidates for out-licensing.

#### Disclaimer

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