

**Press Release** 

For Immediate Dissemination

Glenmark's consolidated revenue rises 14.39% to Rs. 25,813.32 Mn. in Q2 FY 2018 – 19

Consolidated Net Profit rises 93.30% to Rs. 4,140.00 Mn. in Q2 FY 2018-19

Consolidated EBITDA rises 38.71% to Rs. 5,799.85 Mn. in Q2 FY 2018-19

## **Highlights for Q2 FY 2018-19**

- India Business grew by 9.52% to Rs. 7,783.57 Mn.
- US Business grew by 11.44% to Rs. 8,102.47 Mn.
- Europe Business grew by 30.37% to Rs. 2,607.76 Mn.
- ROW Business grew by 21.03% to Rs. 3,051.16 Mn.
- API Business grew by 6.17% to 2,512.08 Mn.

**Mumbai, India, November 13, 2018:** Glenmark Pharmaceuticals Limited, a research-led global integrated pharmaceutical company, today announced its financial results for the second quarter ended September 30 of financial year 2018-19.

In the second quarter ended September 30, 2018, Glenmark's consolidated revenue was at Rs. 25,813.32 Mn (USD 369.97 Mn) as against Rs. 22,565.90 Mn (USD 351.29 Mn), recording an increase of 14.39%.

Consolidated Net Profit was at Rs. 4,140.00 Mn. for the quarter ended September 30, 2018 as compared to Rs. 2,141.20 Mn. in the previous corresponding quarter, registering an increase of 93.30%.

Consolidated EBITDA was at Rs. 5,799.85 Mn. in the quarter ended September 30, 2018 as against Rs. 4,181.22 Mn. in the previous corresponding quarter, an increase of 38.71%.

During the second quarter, the company had a one-time exceptional income of Rs. 1,671.82 Mn.

"Our healthy performance in the second quarter can be attributed to good growth in most of our markets globally. The US business growth was driven by launch of certain limited-competition generic products even though the overall market environment remains challenging. The European business witnessed strong growth due to launch of generic Seretide® Accuhaler® in Nordic countries and other new product launches across the region," said Glenn Saldanha, Chairman & MD, Glenmark Pharmaceuticals. He added, "We continue to invest in building and advancing our R&D pipeline of innovative assets and specialty products, which will spur long-term sustainable growth."

Glenmark's other revenue was at Rs.771.26 Mn. for the second quarter of FY 2018-19, as against Rs. 253.64 Mn. in the previous corresponding quarter, recording an increase of 204.07%. Other revenue



includes out-licensing income on account of the exclusive license agreement signed with Harbour Biomed for the Greater China territory to develop, manufacture and commercialize GBR 1302.

#### **India Formulations**

Sales from the formulation business in India was at Rs. 7,783.57 Mn (USD 111.52 Mn) for the second quarter ended September 30, 2018, as against Rs. 7,106.77 Mn (USD 110.62 Mn) in the previous corresponding quarter, recording a growth of 9.52%.

As per IQVIA MAT September 2018, Glenmark Pharmaceuticals is ranked 13th with a market share of 2.30% in the Indian Pharmaceutical Market. Glenmark's India business has consistently grown ahead of the industry and Glenmark continues to be one of the fastest growing companies as per MAT September 2018 (among top 20 companies). India business strengthened with the company's market share increasing in cardiac, respiratory and anti-diabetic segments during the quarter. Glenmark's consumer care business, consisting of 3 major brands Candid, VWash Plus and Scalpe, grew in excess of 25% in the second quarter of FY 2018-19.

#### **USA Formulations**

Glenmark Pharmaceuticals Inc. U.S.A registered revenue from sale of finished dosage formulations of Rs. 8,102.47 Mn. (USD 116.05 Mn.) for the quarter ended September 30, 2018 as against Rs. 7,270.95 Mn. (USD 113.24 Mn.) in the previous corresponding quarter, recording an increase of 11.44%.

In the second quarter of FY 2018-19, Glenmark was granted final approval and launched Colesevelam Hydrochloride for Oral Suspension and Estradiol Vaginal Inserts USP, 10 mcg.

As of September 30, 2018, Glenmark's marketing portfolio consists of 139 generic products authorized for distribution in the US market. The company currently has 61 applications pending in various stages of the approval process with the US FDA, of which 29 are Paragraph IV applications.

## **Europe Formulations**

Glenmark Europe's revenue for the second quarter FY 2018-19 was at Rs. 2,607.76 Mn (USD 37.37 Mn) as against Rs. 2,000.24 Mn (USD 31.13 Mn) in the previous corresponding quarter, recording an increase of 30.37%.

European region growth was also led by multiple product launches across all key markets. The Western European business continued expanding through increased penetration in the Nordic region, Germany, Spain and the Netherlands. The Nordic region recorded very high growth due to launch of generic version of Seretide® Accuhaler® in Sweden, Denmark and Norway.

## Africa, Asia and CIS Region (ROW)

For the second quarter, revenue from Africa, Asia and CIS region was Rs. 3,051.16 Mn (USD 43.77 Mn) as against Rs. 2,520.93 Mn (USD 39.23 Mn) in the previous corresponding quarter, recording an increase of 21.03%. The Asia and Africa region performed significantly well, growing in excess of 25% in the quarter.



#### **Latin America**

Glenmark's revenue from its Latin American and Caribbean operations was at Rs. 985.03 Mn (USD 14.07 Mn) for the second quarter FY 2018-19, as against Rs. 1,047.23 Mn (USD 16.3 Mn), recording a decrease of 5.94%.

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

Revenue from sale of API globally was Rs. 2,512.08 Mn (USD 36.01 Mn), for the quarter ended September 30, 2018 against Rs. 2,366.14 Mn (USD 36.82 Mn) for the previous corresponding quarter, recording an increase of 6.17%.

### **Research & Development**

Glenmark has a pipeline of 7 innovation assets (5 in clinical; 2 in pre-clinical) and 2 specialty assets currently in development. In addition, Glenmark also has a pipeline of complex generics currently in various stages of development.

# Oncology Assets

**GBR 1302 (HER2xCD3 bsAb):** The GBR 1302 Phase 1, first in human study to determine maximum tolerated dose (MTD) in patients with HER2 positive cancers is ongoing. Dose escalation continues at 9 participating clinical trial sites across Germany and the US.

**GBR 1342 (CD38xCD3 bsAb):** For GBR 1342, a Phase 1, first in human study to determine MTD in patients with Multiple Myeloma is ongoing. The study is currently enrolling patients in Cohort 8 with patients being already identified for enrolment into Cohort 9.

Glenmark also recently announced the decision to launch a Phase 1 trial in solid tumors for GBR 1342 based on non-interventional human translational data. The company intends to file an Investigational New Drug (IND) application with the US FDA and initiate a clinical trial in CY 2019.

**MAP4K1 Inhibitor:** Glenmark obtained exclusive global rights to a small molecule, oncology compound based on Antigen Presenting Cell (APC) biology, through a licensing agreement signed with APC Therapeutics Inc. in 2017. The lead compound is currently progressing well through the pre-clinical studies and the company is targeting to initiate clinical development in FY 2019-20.

# Immunology Assets

**GBR 830 (OX40 antagonist):** A Phase 2b study of GBR 830 in 392 patients has been initiated in adults with moderate to severe Atopic Dermatitis, with 30 trial sites actively open to enrol patients in the US and Canada. Glenmark has initiated activities in the EU and enrolment is expected to start by January 2019. Top-line results of the Phase 2b study are expected in Q3 FY 2019-20.



In addition to Atopic Dermatitis, Glenmark is also currently evaluating GBR 830 for a study in patients with systemic lupus erythematosus (SLE). The company has also initiated pre-clinical exvivo translational studies to evaluate GBR 830 in patients suffering from ulcerative colitis (UC).

**GRC 39815 (RORyt inhibitor):** GRC 39815 is a NCE currently being evaluated as an inhaled compound for the possible treatment of Chronic Obstructive Pulmonary Disorder (COPD). The compound is currently in pre-clinical development and the company plans to initiate a Phase 1 study in H1 FY 2019-20.

#### Pain Assets

**GRC 27864 (mPGES-1 inhibitor):** The Phase 2b study of GRC 27864 in 624 patients with osteoarthritic pain, is progressing as per plan, with 33 active sites in India and more than 100 patients recruited for the study. Top-line results of the Phase 2b study are expected to be available in H1 FY 2019-20.

**GRC 17536 (TRPA1 antagonist):** GRC 17536 has shown positive data in a Phase 2a proof of concept study in patients with painful diabetic neuropathy conducted in Europe and India. Phase 2 enabling toxicology studies are ongoing and the compound has shown a good safety profile supporting further development. Glenmark is targeting to initiate a Phase 2b dose range finding study in Neuropathic Pain in FY 2019-20.

### Specialty Assets

Glenmark has 2 specialty assets currently in development, which includes Ryaltris™, Glenmark's first NDA filed in the U.S., and a biosimilar for Xolair®.

**Ryaltris™:** During the second quarter, Glenmark announced US FDA's acceptance of the company's first New Drug Application (NDA) for Ryaltris™ (olopatadine hydrochloride [665 mcg] and mometasone furoate [25 mcg]), indicated for treatment of seasonal allergic rhinitis (SAR) in patients 12 years of age and older. The Prescription Drug User Fee Act (PDUFA) target action date for completion of the FDA review is March 21, 2019.

**GBR 310:** During the second quarter, Glenmark announced results from a Phase 1 study that suggest similarity in pharmacokinetic, pharmacodynamic, safety and immunogenicity profiles between Glenmark's proposed biosimilar, GBR 310, and the reference product omalizumab, marketed in the US under the brand name Xolair<sup>®1</sup>. Glenmark expects to meet with the US FDA in H2 CY 2018, with the goal of advancing the development of GBR 310. The company targets to file/initiate the Phase 3 study in H1 FY 2019-20.

<sup>1</sup> Xolair is a registered trademark of Genentech USA, Inc. and Novartis Pharmaceuticals Corporation indicated for the treatment of moderate to severe persistent asthma in patients six years of age and older with a positive skin test or in vitro reactivity to a perennial aeroallergen and symptoms that are inadequately controlled via inhaled corticosteroids; and for the treatment of chronic idiopathic urticaria in adults and adolescents 12 years of age and older who remain symptomatic despite H1 antihistamine treatment.



#### **About Glenmark Pharmaceuticals Ltd.:**

Glenmark Pharmaceuticals Ltd. (GPL) is a research-driven, global, integrated pharmaceutical organization. It is ranked among the top 75 Pharma & Biotech companies of the world in terms of revenue (SCRIP 100 Rankings published in the year 2018). Glenmark is a leading player in the discovery of new molecules both NCEs (new chemical entity) and NBEs (new biological entity). Glenmark has several molecules in various stages of clinical development and is focused in the areas of oncology, dermatology and respiratory.

The company has a significant presence in the branded generics markets across emerging economies including India. Glenmark has 16 manufacturing facilities across five countries and has six R&D centers. The Generics business of Glenmark services the requirements of the US and Western European markets. The API business sells its products in over 80 countries, including the US, various countries in the EU, South America and India. For more information visit www.glenmarkpharma.com

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