

Press Release

For Immediate Dissemination

Glenmark's consolidated revenue at Rs. 23,228.79 Mn. for Q1 FY 2019 – 20**Consolidated Net Profit at Rs. 1092.81 Mn. for Q1 FY 2019 – 20****Consolidated EBITDA (excluding other income) at Rs. 3419.12 Mn. for Q1 FY 2019 – 20****Highlights for Q1 FY 2019 – 20**

- India Business grew by 13.41% to Rs. 7,522.19 Mn.
- US Business grew by 3.86% to Rs. 7,308.93 Mn.
- Europe Business grew by 10.50% to Rs. 2,428.54 Mn.
- ROW Business grew by 5.43% to Rs. 2,587.27 Mn.
- Latin America Business de-grew by 16.89% to Rs. 811.24 Mn.
- API Business grew by 9.77% to 2,306.01 Mn.

Mumbai, India; August 13, 2019: Glenmark Pharmaceuticals Limited, a research-led global integrated pharmaceutical company, today announced its financial results for the first quarter ended June 30 of financial year 2019 – 20.

For the first quarter ended June 30, 2019, Glenmark's consolidated revenue was at Rs. 23,228.79 Mn. (USD 334.22 Mn.) as against 21,656.17 Mn. (USD 323.76 Mn.), recording an increase of 7.26%.

Consolidated Net Profit was at Rs. 1092.81 Mn. for the quarter ended June 30, 2019 as compared to Rs. 2329.90 Mn. in the previous corresponding quarter, registering a decrease of 53.10%. The figures are not comparable as the last financial year included onetime forex gain of Rs. 1382.16 Mn.

Consolidated EBITDA (excluding other income) was at Rs. 3419.12 Mn. in the quarter ended June 30, 2019 as against Rs. 3468.83 Mn. in the previous corresponding quarter, registering a decrease of 1.43%.

"Our first quarter performance in key markets like India and Europe was impressive on account of new product launch and partnership deals. However, the overall performance was impacted due to moderate performance in the U.S. and subdued performance in LATAM," said Glenn Saldanha, Chairman & MD, Glenmark Pharmaceuticals. He further added, "We have a strong innovation pipeline of six assets in various stages of development in the areas of immunology, oncology and pain management. We will continue to steadily invest in the new innovation business with an objective of accelerating the pipeline towards commercialization."

India Business

Sales from the formulation business in India for the first quarter of FY 2019-20 was at Rs. 7,522.19 Mn (USD 108.23 Mn) as against Rs. 6,632.90 Mn (USD 99.16 Mn) in the previous corresponding quarter, recording a growth of 13.41%.

According to IQVIA Q1 FY 2019-20, Glenmark's India business recorded growth of ~12% as it continued to outperform the industry growth. As per IQVIA MAT June 2019, Glenmark's India formulation business is ranked 14th, with market share of 2.18%. The company now has 9 brands among the 'Top 300 Brands in the IPM.'

In April 2019, Glenmark launched its novel, patent protected and globally-researched sodium glucose co-transporter-2 (SGLT2) inhibitor Remogliflozin etabonate (Remogliflozin) in India. As per IQVIA June 2019, the sales for Remogliflozin is already tracking ~INR 2 cr per month, in less than 2 months from launch.

In July 2019, Glenmark announced that it has entered into a non-exclusive sub-licensing agreement with Torrent Pharmaceuticals Limited to co-market Remogliflozin in India. Glenmark is also targeting to close one more co-marketing deal for Remogliflozin in the second quarter. The Company is also developing various line-extensions for Remogliflozin which would be launched over the next 12 months.

Glenmark's consumer care business continued its strong growth trajectory registering growth of around 27% in Q1 FY 2019-20. Key brands like Candid Powder and VWash recorded high growth and continue to hold a dominant market share in their respective markets. Multiple line-extensions were launched in the first quarter of FY 2019-20, such as VWash Bikini Line & Scalpe Pro Anti-Dandruff shampoo.

USA Business

Glenmark Pharmaceuticals Inc., USA registered revenue from the sale of finished dosage formulations of Rs. 7,308.93 Mn (USD 105.16 Mn) for the quarter ended June 30, 2019 as against revenue of Rs. 7,037.48 Mn (USD 105.21 Mn) for the previous corresponding quarter, recording an increase of 3.86%.

The Company anticipates two significant generic approvals (a limited competition injectable product and a topical product with CGT designation) in the second quarter of FY 2019-20 which would provide impetus to the US generics business. The Company filed three ANDA applications with the U.S. FDA in the first quarter, and plans to file an additional four applications in the forthcoming quarter.

Glenmark's marketing portfolio through June 30, 2019 consists of 157 generic products authorized for distribution in the U.S. market. The Company currently has 58 applications pending in various stages of the approval process with the US FDA, of which 32 are Paragraph IV applications.

Africa, Asia and CIS Region (ROW) Business

For the first quarter of FY 2019-20, revenue from Africa, Asia and CIS region was Rs. 2,587.27 Mn (USD 37.23 Mn) as against Rs. 2,454.14 Mn (USD 36.69 Mn) for the previous corresponding quarter, recording an increase of 5.43%.

Europe Business

Glenmark Europe's operations revenue for the first quarter of FY 2019-20 was at Rs. 2,428.54 Mn (USD 34.94 Mn) as against Rs. 2,197.86 Mn (USD 32.86 Mn) recording an increase of 10.50%.

During the first quarter, the western European business continued expanding through increased penetration in the UK, Germany, Spain and NL while Nordic countries witnessed some de-growth. Overall the western European business recorded a growth of 10%. The central and eastern European business recorded moderate growth in the first quarter. During the first quarter, multiple new products were launched across all major countries of the Europe region. The Company also signed two in-licensing agreements during the first quarter.

Latin America Business

Glenmark's revenue from its Latin American and Caribbean operations was at Rs. 811.24 Mn (USD 11.67 Mn) for the first quarter of FY 2019-20, as against Rs. 976.11 Mn (USD 14.59 Mn), recording a decrease of -16.89%. The Company's overall performance remained subdued for the region in the first quarter.

Glenmark Life Sciences Ltd. (GLS) – API Business

For the first quarter of FY 2019-20, external sales for Glenmark Life Sciences was at Rs. 2,306.01 Mn (USD 33.18 Mn) as against Rs. 2,100.78 Mn (USD 31.41 Mn), recording growth of 9.77% over the corresponding period last year.

Innovation New Company (NewCo)

The new innovation company headquartered in the US will be a wholly-owned subsidiary of Glenmark, focused on discovery and development of novel, first-in-class treatments in the therapeutic areas of Immunology, Oncology and Pain.

The subsidiary creation process is on track with various work streams such as HR, Finance/Legal, Branding, and IT systems transition currently under progress. The Company expects to announce the name of the new innovation organization by mid-October 2019. NewCo has also instituted an independent board of directors which would govern the functioning of the new innovation organization.

NewCo's current innovation pipeline consists of 6 assets, including new chemical entities (NCEs) and new biological entities (NBEs), in various stages of development in the areas of immunology, oncology and pain management.

Amongst the 5 assets in clinical development, 2 assets are currently in Phase 2b studies (GBR 830 and GRC 27864), 1 asset is gathering data in anticipation of entering Phase 2b (GRC 17536), and 2 oncology assets are in Phase 1a/1b. The remaining asset (GRC 5xxxx) is currently in pre-clinical development. Of the 6 assets, 2 assets have shown positive clinical proof-of-concept (GBR 830 and GRC 17536).

Immunology

GBR 830 (OX40 antagonist)

- A Phase 2b study of GBR 830 has been initiated and top-line results of the Phase 2b study in Atopic Dermatitis are expected to be available in H1 CY 2020.
- Abstract to the 2019 American College of Rheumatology (ACR) submitted showing that GBR 830 is a suitable drug candidate for treatment of systemic lupus erythematosus (SLE). Initiation of Phase 2b/3 study in patients with SLE is expected in CY 2020.
- In addition, evaluation of GBR 830 for the treatment of multiple immunology indications such as Rheumatoid Arthritis (RA), systemic sclerosis/scleroderma (SSc), Hidradenitis Suppurativa (HS), Lupus Nephritis (LN), Ulcerative Colitis (UC), is ongoing.

Pain Management

GRC 27864 (mPGES-1 inhibitor)

- GRC 27864 is a non-opioid, selective, and orally bioavailable inhibitor of microsomal prostaglandin E synthase-1 (mPGES-1). Enrolment of patients for a Phase 2b study is progressing as per plan and top-line results of the Phase 2b study are expected to be available in Q1 CY 2020.

GRC 17536 (TRPA1 antagonist)

- A positive Phase 2a proof of concept study of GRC 17536 conducted in Europe and India in patients with painful diabetic neuropathy has been completed. The Company is targeting to initiate a Phase 2b dose range finding study in neuropathic pain in CY 2020.

Oncology

GBR 1302 (HER2xCD3 bsAb)

- The GBR 1302 Phase 1, first-in-human study with bi-weekly dosing to determine the maximum tolerated dose (MTD) in patients with HER2-positive cancers has completed enrolment as of May 2019.
- The company plans to initiate a GBR 1302 Phase 1 study to evaluate a weekly dosing regimen in H2 CY 2019.

GBR 1342 (CD38xCD3 bsAb)

- For GBR 1342, a Phase 1, first-in-human study to determine the MTD in a bi-weekly dosing regimen in patients with refractory multiple myeloma is ongoing. Cohorts 1-9 have been completed, and the study continues with the enrolment of patients into Cohort 10.

- The company has amended the current protocol to include a weekly dosing regimen in the current study and enrolment into the weekly dosing regimen is expected to begin in H2 CY 2019.

GRC 5xxxx

- The Company is developing GRC 5xxxx, a MAP4K1 inhibitor compound which has the potential to be used as a monotherapy or in combination with approved therapies to address unmet needs in cancer treatment.
- The compound is currently progressing through pre-clinical studies. The Company is targeting to initiate Phase 1 studies in H2 CY 2020.

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About Glenmark Pharmaceuticals

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.

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