



# **MILESTONES**

## HIGHTLIGHTS - API Q1 FY 2017-18 (April - June 2017)

- During the quarter, Glenmark filed 1 US DMF Olopatadine Hydrochloride and 1 EU CEP – Pirfenidone
- An audit was successfully concluded recently at Glenmark Dahej, our API facility situated in Gujarat, India, by the Japanese PMDA
- Glenmark accelerated the development and validation schedule of key APIs like Crisaborole and Liftegrast which are on track for DMF filing during FY2017-18

### **R&D HIGHTLIGHTS:**

- Reported positive data from Phase 3 SAR study in Mar 2017 for GSP 301, a specialty combination of a steroid and an anti-histamine administered intranasally for the treatment of seasonal allergic rhinitis in adults and adolescents
- Phase 2 study completed dosing for GSP 304, a LAMA administered by nebulization for the long term, once-daily, and maintenance treatment of bronchospasm associated with COPD
- GBR 310 is a biosimilar candidate being developed for the treatment of asthma and chronic idiopathic urticaria. Phase 1 study has been initiated to assess its pharmacokinetics in comparison to the reference product. This molecule has the potential to become the 1st biosimilar candidate for Xolair
- GBR 830, an OX40R receptor antagonist targeting activated T cells and effector memory T cells, is under development for the treatment of atopic dermatitis and other autoimmune disorders.
- GBR 1302, GBR 1342 and GBR 1372 are based on BEAT® technology engaging two targets with a bispecific antibody to target cancer cells by the redirection of cytolitic
- GBR 8383 is a new type of highly potent OX40R receptor agonist which potentially represents the first in a new class of potent Immuno-Oncology molecules

## **OTHER HIGHLIGHTS:**

# ----- INDIA -----

- The India business strengthened itself in cardiac, respiratory, derma and anti-diabetic therapeutic segments.
- Glenmark presently has 8 brands among the 'Top 300 Brands of the Indian Pharmaceutical Market.'

## ----- USA -----

- 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 in December 2016 with a period of 180 day exclusivity which continued during the fourth quarter.
- 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.



#### Dear Doctor.

We have come a long way in a short time. 16 years ago, we were a USD 31 Mn Company focused on the Indian pharma market. Today, we are a USD 1.4 bn research led global pharma organization with over 13,000 employees in 50 countries, with 70% of our revenues from international markets. Our objective is to earn 30% of our revenues from specialty and innovative products by 2025. Our innovation program, that we began investing over a decade ago, has begun to deliver results with new molecules, currently in different stages of development, in the three focus areas of oncology, respiratory and dermatology. In parallel, we are growing in size and reach, expanding our manufacturing footprint and providing differentiated products to customers globally. We hope that you will continue to support us in our exciting journey.



### ----- EUROPE -----

- 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.
- The Western European region recorded constant currency growth of 18%. During the 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.

### ---- RUSSIA & CIS --

- 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

# ---- AFRICA ---

• 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.

### ---- ASIA -----

- 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.



# **BEAT** - Bispecific Engagement by Antibodies based on the T cell receptor

BEAT® (Bispecific Engagement by Antibodies based on the T cell receptor) is Glenmark's proprietary technology for the production of bi-specific antibodies (bsAbs), leading to engagement and activation of naturally occurring T cells when bridging to tumor cells. Glenmark's scientists have developed a promising pipeline of bi-specific monoclonal antibodies (bsAbs) on the BEAT® platform in the category of immunotherapy i.e. drugs that recruit the immune system to fight disease. Given their dual specificity, they simultaneously bind to targets in the immune system and on tumor cells. This allows T cells - essentially, soldiers of the immune system – to destroy tumor cells more completely and faster than conventional mAbs.