

## Management Discussion and Analysis for the Fourth quarter of FY 2017 – 18

## **Revenue Figures – Consolidated**

/Rs	In	Millions)
ins.		winnonsy

	Fourth quarter ended March 31			Twelve months ended March 31		
	FY 2017 – 18	FY 2016 – 17	Growth (%)	FY 2017 – 18	FY 2016 – 17	Growth (%)
India	6,086.70	5,769.32	5.50	25,142.52	23,037.77	9.14
US	6,995.59	10,004.46	-30.08	32,075.72	37,006.63	-13.32
Rest of the World (ROW)	2,985.36	2,889.37	3.32	10,992.24	9,887.86	11.17
Europe	3,189.56	2,297.80	38.81	9,058.10	7,101.35	27.55
Latin America	1,276.23	1,339.88	-4.75	4,066.95	5,181.22	-21.51
ΑΡΙ	2,048.62	1,997.24	2.57	8,778.91	8,094.10	8.46
Total	22,582.06	24,298.07	-7.06	90,114.44	90,308.93	-0.22
Other Revenue	216.10	273.76	-21.06	916.26	1,547.88	-40.81
Consolidated Revenue	22,798.16	24,571.83	-7.22	91,030.70	91,856.81	-0.90

Average conversion rate in 12M FY 2017 – 18 considered as INR 64.39/USD 1.00 Average conversion rate in 12M FY 2016 – 17 considered as INR 66.97/USD 1.00 USD figures are only indicative



#### Review of Operations for the quarter ended March 31, 2018

For the fourth quarter ended March 31, 2018, Glenmark's consolidated revenue was at Rs. 22,798.16 Mn (USD 354.67 Mn) as against Rs. 24,571.83 Mn (USD 367.20 Mn) recording a decrease of -7.22%.

For the twelve months ended March 31, 2018, Glenmark's consolidated revenue was at Rs. 91,030.70 Mn (USD 1,413.68 Mn) as against Rs. 91,856.81 Mn (USD 1,371.62 Mn) recording a decrease of -0.90%.

#### India

Sales from the formulation business in India for the fourth quarter ended March 31, 2018 was at Rs. 6,086.70 Mn (USD 94.70 Mn) as against Rs. 5,769.32 Mn (USD 86.22 Mn) in the previous corresponding quarter, recording a growth of 5.50%.

As per IQVIA MAT March 2018, Glenmark Pharmaceuticals (IF) is ranked 13th with a market share of 2.29%. Glenmark is the 2<sup>nd</sup> fastest growing company as per MAT March 2018 (among top 20 companies). Glenmark has 8 brands among the 'Top 300 Brands in the Indian Pharmaceutical Market.' The India business strengthened itself in the following segments with growth in market share from IQVIA MAT March 2017 to MAT March 2018 respectively. The Cardiac segment market share increased from 3.97% to 4.26%; the Respiratory segment market share rose from 4.52% to 4.75%; the Anti-diabetic segment market share changed from 1.69% to 1.64%; and the Derma segment market share increased from 9.17% to 9.20%.

During the quarter, Glenmark launched the biosimilar of Adalimumab (Brand name ADALY) under a licensing agreement with Cadila Healthcare Ltd., the Zydus group for the treatment of Plaque Psoriasis and Rheumatoid Arthritis. ADALY (Adalimumab) is a TNF inhibiting, antiinflammatory biologic that binds to tumor necrosis factor (TNFalpha) and reduces inflammatory response. Globally, Adalimumab is the number one selling pharmaceutical product.

The Company also launched Nourkrin<sup>®</sup> Woman tablets, through an exclusive licensing agreement with Denmark-headquartered firm Pharma Medico. Nourkrin<sup>®</sup> Woman contains Marilex<sup>®</sup>, a unique and proprietary scientific formula, rich in specific proteoglycans (PG) essential for hair follicle development, which helps in normalizing, supporting and maintaining the Hair Growth Cycle. Nourkrin<sup>®</sup> Woman is a proven formula, based on more than 56 scientific studies and is recognized by leading regulatory agencies globally. Nourkrin<sup>®</sup> is the number one product in UK and Europe for hair loss management and is available in more than 40 countries worldwide. Nourkrin Woman addresses the core issue of normalizing the hair growth cycle through a convenient route of administration.

Glenmark is a leader in dermatology in India and has been at the forefront of introducing new molecules to meet various unmet needs of patients. Recently the company introduced Aprezo (Apremilast) for psoriasis. The launch of ADALY and Nourkrin<sup>®</sup> Woman further re-emphasizes the Company's focus towards developing treatments for unmet medical needs in dermatology.



Glenmark also announced an exclusive licensing agreement with Helsinn Group ("Helsinn"), a Swiss pharmaceutical group focused on building quality cancer care products, to introduce AKYNZEO<sup>®</sup> in India and Nepal. AKYNZEO<sup>®</sup>, an oral fixed combination of netupitant 300mg and palonosetron 0.5mg in capsule form, is used for prevention of chemotherapy-induced nausea and vomiting (CINV). The licensing agreement with Glenmark for AKYNZEO<sup>®</sup> represents Helsinn's first such agreement in India. Glenmark will have exclusive marketing rights for AKYNZEO<sup>®</sup> in India and Nepal. Glenmark has received marketing approval for AKYNZEO<sup>®</sup> from the Central Drugs Standard Control Organization (CDSCO).

#### India – Glenmark Consumer Care Business

Glenmark forayed into the over-the-counter (OTC) space a few years ago. In a short time, the company has built a sizeable OTC business driven by its 3 major brands operating in the consumer space now – Candid, VWash Plus and Scalpe+. Candid Dusting Powder, the 30 year old flagship brand for the company has been a prescription leader for the treatment of anti-fungal skin infections and is now a leading product even in the OTC business.

Through the introduction of its brand VWash Plus, Glenmark has successfully created the female intimate hygiene category in India. The company further expanded its product offering through the introduction of VWash Wow San Naps. VWash's extension in to INR 3500 Cr Sanitary Napkin category further propels the brand towards its vision of 'Owning the Intimate Hygiene Space'. VWash WOW has been very well received across the sales channels within three months of launch.

Over a short period of time, Glenmark's consumer care business has grown its topline in excess of INR 150 Cr. As per MAT March 2018, Glenmark's leading brand Candid recorded 18.1% value growth and market share of about 56%. Scalpe is also ranked no. 1 in its operating market with a market share of 15% as per MAT March 2018. VWash Plus brand recorded value growth of 24% and a market share of 42% for FY18 across all sales channels.

#### **USA Formulations**

Glenmark Pharmaceuticals Inc., U.S.A. registered revenue from the sale of finished dosage formulations of Rs. 6,995.59 Mn (USD 108.87 Mn) for the quarter ended March 31, 2018 against revenue of Rs. 10,004.46 Mn (USD 149.51 Mn) for the previous corresponding quarter, recording a decrease of -30.08%. The sales are not comparable to the corresponding quarter of the previous financial year as Glenmark through its partner Endo had launched Ezetimibe, generic version of ZETIA<sup>®</sup> (Merck) in the United States in December 2016 and was entitled to an exclusivity on the product.

In the fourth quarter of fiscal year 2017-18, Glenmark was granted final approval Clobetasol Propionate Spray, 0.05%, the generic version of Clobex<sup>®</sup> Spray, 0.05% of Galderma Laboratories, L.P. In the fourth quarter, Glenmark filed seven ANDA's with the U.S. FDA, two of which are first-to-file; and plans to file three ANDA applications in the forthcoming quarter.

In the fiscal year 2017-18, Glenmark was granted approval of 21 Abbreviated New Drug Applications (ANDA), comprised of 18 final approvals and 3 tentative approvals. Notable approvals include: Aprepitant Capsules USP, Atomoxetine Capsules USP, Nitroglycerin Sublingual



Tablets and Propafenone Hydrochloride Extended-Release Capsules USP. The Company filed a total of 16 ANDA applications with the U.S. FDA throughout the fiscal year.

The Pithampur plant at Indore was inspected by the USFDA from May 14, 2018 to May 24, 2018. The plant received 5 observations which was communicated via the Form 483. The company will respond to the observations within the stipulated time frame. Further, the company received the approval for Colesevelam Hydrochloride Tablets, 625 mg, the generic version of Welchol<sup>®</sup> Tablets, 625 mg which is manufactured at the same plant on May 18, 2018. Glenmark was also granted final approval Tacrolimus Ointment, 0.1%, the generic version of Protopic<sup>®</sup>1 Ointment, 0.1%, of Leo Pharma AS. The company has already commenced supplies of these products to the US market.

Glenmark's marketing portfolio through March 31, 2018 consists of 131 generic products authorized for distribution in the U.S. market. The Company currently has 62 applications pending in various stages of the approval process with the US FDA, of which 28 are Paragraph IV applications.

Glenmark's manufacturing facility in the USA was commissioned in 2014 at Monroe Corporate Center, North Carolina. The Monroe plant in the US also underwent an inspection by the USFDA from May 14, 2018 to May 18, 2018. The plant received the Form 483 with two observations. The company will respond to the observations within the stipulated time frame. This was the first inspection by the USFDA at the Monroe plant. The company expects to begin commercial supplies of oral solid products from H2 FY19. Glenmark also plans to file injectables and nebulizers from the Monroe facility during FY19.

During the quarter, Glenmark announced an exclusive agreement with Sam Chun Dang Pharm. Co. Ltd. (SCD), to develop, manufacture and market a portfolio of ophthalmic products in the U.S. and Canada. Under this agreement, these products will be developed and manufactured by SCD in South Korea. Glenmark will seek all market authorizations and commercialize the products in North America. The Company targets to file around six ANDAs beginning in the first half of 2019 for the licensed SCD ophthalmic products. According to IQVIA sales figures, the U.S. brand sales for the six products was approximately \$1.7 billion for calendar year 2017.

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

#### Africa, Asia and CIS Region (ROW)

For the fourth quarter, revenue from Africa, Asia and CIS region was Rs. 2,985.35 Mn (USD 46.44 Mn) as against Rs. 2,889.37 Mn (USD 43.18 Mn) for the previous corresponding quarter, recording an increase of 3.32%.

According to IQVIA MAT March'18 data, Glenmark Russia shows de-growth of -5.7% in value vs. overall market growth of 3.3 % and ranks 41 MAT March'18 in the retail segment of the Russian pharmaceutical market. Lower than market growth being attributed to decline in demand for two key products: Ascoril (low cough & cold season) and Oflomil nail lacquer (competitor activity and launch of new amorolfine generics).

As a result of the strong position of Glenmark Russia in the dermatology segment (retail), the company continues to secure its position in this segment and ranks in the Top-10 of all derma companies present in the market, with MAT March 2018 rank being 9. In the respiratory space,



Glenmark continues to secure a strong position and ranks 4 MAT March'18 amongst the companies present on the expectorants market (retail segment) of the local pharmaceutical market. Key markets across the CIS region such as Ukraine and Kazakhstan recorded high double-digit secondary sales growth for the company.

The Asia region secondary sales growth was led by key subsidiaries such as Malaysia and the Philippines. The Glenmark Africa region also posted strong secondary sales growth in the fourth quarter aided by good performance across most of the subsidiaries.

#### **Europe Formulations**

Glenmark Europe's operations revenue for the fourth quarter ended March 31, 2018 was at Rs. 3,189.56 Mn (USD 49.59 Mn) as against Rs. 2,297.80 Mn (USD 34.33 Mn) recording an increase of 38.81%.

The Europe subsidiary performed well during the quarter. The Western European business continued expanding through increased penetration in the UK, Netherlands, Spain and further expansion of sales and product portfolio in Germany. The company also expanded in to the Nordic countries through a new Legal Entity in Sweden. The Central Eastern European region recorded secondary sales growth of 19% during the quarter.

The overall regional growth was led by multiple new product launches across all key markets. Glenmark launched 5 products in the UK, 4 products in Sweden and 3 products each in the Netherlands, Germany and Spain. Maloff Protect (250mg/100mg atovaquone/proguanil film-coated tablets), anti-malarial medication, launched as a pharmacy license in the United Kingdom during Q2 FY18 continues to perform well.

During the third quarter FY18, Glenmark had successfully closed the decentralized registration procedure for generic Seretide<sup>®</sup> Accuhaler<sup>®</sup> in the Nordic region, including Sweden, Denmark, Norway, Finland and Iceland. This will be Glenmark's first inhaled Respiratory product approval in Europe, and re-enforces Glenmark's commitment in the respiratory area.

Subsequently, Glenmark is the first generic company to receive regulatory approval for substitution in Denmark for its generic of Seretide<sup>®</sup> Accuhaler<sup>®</sup> and has subsequently launched the product.

#### Latin America

Glenmark's revenue from its Latin American and Caribbean operations was at Rs. 1,276.23 Mn (USD 19.85 Mn) for the fourth quarter ended March 31, 2018 as against Rs. 1,339.88 Mn (USD 20.02 Mn), recording decrease of -4.75%. The overall performance in the region remained challenging particularly in larger markets such as Brazil and Mexico. Going forward the Company is working towards ensuring approval for key pipeline products particularly in the respiratory segment to boost the overall market growth in Latin America.



## Active Pharmaceutical Ingredients (API)

Revenue from sale of API to regulated and semi-regulated markets globally was Rs. 2,048.62 Mn (USD 31.87 Mn), for the quarter ended March 31, 2018 against Rs. 1,997.24 Mn (USD 29.85 Mn) for the previous corresponding quarter, recording an increase of 2.57%.

Glenmark forayed in to the API business in 2003 and over the last 15 years has built a large business based on strong product selection, focus on key regulated markets, maintaining high operational efficiency and a strong compliance culture. The company has robust R&D capabilities in API for developing an attractive pipeline and achieving cost efficiencies to overcome external market challenges.

Key APIs driving sales for Glenmark in FY18 were Perindopril, Lercanidipine, Amiodarone, Etoricoxib & Adapalene. During the quarter Glenmark also successfully concluded the US FDA audit of the API plant at Mohol and is awaiting the EIR from the agency.

#### **Research & Development**

The company has a pipeline of 7 new molecular entities (NMEs), which includes 2 new chemical entities (NCEs), 4 new biological entities (NBEs) and a biosimilar candidate, in various stages of clinical development focused in the therapeutic areas of oncology, respiratory and dermatology.

Glenmark's clinical development centres are based in Paramus, New Jersey, and research centres are based in Navi Mumbai, India and Neuchâtel, Switzerland. Spread over 125,000 square feet the R&D centre 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 including medicinal chemistry, process and analytical chemistry, *in vitro* and *in vivo* studies and project management. Glenmark's dedicated R&D centre for biologics in Switzerland has end-to-end capabilities to discover NBE's and to support clinical development and the centre is also fully equipped to manufacture and supply clinical trial material.

#### **BEAT®** Technology

BEAT<sup>®</sup> (Bispecific Engagement by Antibodies based on the T cell receptor) is Glenmark's proprietary technology for the production of bispecific antibodies (bsAbs). With BEAT<sup>®</sup> technology, Glenmark's scientists have been able to overcome past production obstacles encountered with bsAbs and efficiently manufacture these molecules on a clinical and commercial scale. Preclinically, BEAT<sup>®</sup> bsAbs demonstrate the potential for more potent activity compared to existing therapeutic antibodies. Additionally, structural similarity to naturally-occurring antibodies may result in a normalized IgG half-life and less immunogenicity.

#### ONCOLOGY ASSETS

Quarterly Highlights:

• The GBR 1302 Phase 1, first in human study to determine maximum tolerated dose (MTD) in patients with HER2 positive cancers is actively enrolling. Dose escalation



continues at nine participating clinical trial sites across Germany and the U.S. The study is currently dosing patients in Cohort 9 and will continue until MTD is reached.

- Glenmark announced in May that the Phase 1 trial will be expanded to explore higher doses of GBR 1302 and to examine potential clinical benefit of a onceweekly dosing regimen. Additionally, based on predictive response rates observed in *ex vivo* translational studies, a Phase 1b/2 study is being designed and will include an expansion cohort of HER2 positive metastatic breast cancer patients.
- Translational data in trastuzumab-resistant cancers will be presented at the 2018 Annual Meeting of the American Society of Clinical Oncology
- For GBR 1342, a Phase 1, first in human study to determine MTD in patients with multiple myeloma dosed its first patient in December 2017. The study is currently dosing patients in Cohort 5 with patients being already identified for enrolment into Cohort 6. Clinical sites continue to identify patients for possible enrolment into the study. Up to 10 cohorts are planned for this MTD portion of the study.
  - The study's primary objective is to assess the safety and tolerability of increasing doses of GBR 1342. Additional study objectives include assessment of biomarkers, immunogenicity and measures of anti-tumor activity.
- GBR 1372 is currently in pre-clinical development and is expected to progress to the clinics in H1 CY19.

#### GBR 1302

GBR 1302, a HER2xCD3 bsAb, is the first clinical candidate based on Glenmark's proprietary BEAT<sup>®</sup> 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 treatment-resistant cancers. A Phase 1 study is underway to determine MTD. Dosing escalation is continuing.

Patients enrolled in the study receive intravenous GBR 1302 on Day 1 and Day 15 in 28-day treatment cycles at escalating doses until maximum-tolerated dose is achieved. Preliminary biomarker data demonstrate modulation of peripheral T cell populations and cytokines. Some subjects treated at the higher doses experienced cytokine release syndrome, which was mild and transient. Dose escalation is ongoing.

#### GBR 1342

GBR 1342, a CD38xCD3 bsAb based on Glenmark's proprietary BEAT<sup>®</sup> platform targets CD38, a clinical target in multiple myeloma and other malignancies of hematopoietic origin, as well as a variety of solid tumors. 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. A Phase 1 study is underway.

#### GBR 1372

GBR 1372 is an EGFRxCD3 bsAb 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. GBR 1372 is currently in preclinical development.

## DERMATOLOGY ASSET

Quarterly Highlights:

- A Phase 2b study of GBR 830 has been initiated in the U.S. and Europe with trial enrolment expected to begin in June 2018.
- Biomarker data from a Phase 2a proof-of-concept study were presented orally at the International Investigative Dermatology (IID) Meeting in May 2018.
  - New data from the study demonstrated that treatment with GBR 830 resulted in observable modulation of biomarkers with both the acute and chronic stages of atopic dermatitis
  - The GBR 830 presentations at IID 2018 include one oral presentation and three poster presentations
- Glenmark is currently evaluating GBR 830 for a study in patients with systemic lupus erythematosus (SLE)
- The Company has also initiated pre-clinical Ex-vivo translational studies to evaluate GBR 830 in patients suffering from Ulcerative Colitis (UC)

## GBR 830

GBR 830, an anti-OX40R monoclonal antibody, was discovered at the Glenmark Biologics Research Centre located in Switzerland and is in clinical development by Glenmark USA. GBR 830 is being developed to target and inhibit pathologically activated T cells and effector memory T cells which are involved in a variety of autoimmune and chronic inflammatory disorders. The lead indication being evaluated for GBR 830 is moderate-to-severe atopic dermatitis (AD).

Glenmark completed a Phase 2a study evaluating GBR 830, relative to placebo, in adults with moderate-to-severe AD with history of inadequate response to topical therapies. Although not powered for statistical differences between GBR 830 versus placebo, data from this study suggest clinically meaningful improvement of symptoms that is continuous and sustained, with consistency observed between biological and clinical response. The overall safety profile of GBR 830 was similar to placebo. The most common treatment-related adverse event was headache, with no clinically meaningful differences between GBR 830 and placebo (4 percent and 6 percent, respectively).

Based on the results of this Phase 2a study, Glenmark is firmly committed to advancing GBR 830 for patients with AD and plans to initiate a Phase 2b trial in the U.S. and Europe in Q1 of FY 2019. Glenmark is targeting a BLA filing for GBR 830 in 2022. Evaluation 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**

#### Quarterly Highlights:

- Glenmark announced the filing submission of the company's first New Drug Application for Ryaltris<sup>™</sup> (olopatadine hydrochloride (665 mcg) and mometasone furoate (25 mcg)) nasal spray suspension for the treatment of symptoms of patients over 12 years of age and older with seasonal allergic rhinitis (SAR) on May 21.
  - Glenmark has studied Ryaltris (formerly GSP 301 nasal spray) in seven clinical trials involving more than 4,000 patients.
  - Glenmark expects the FDA will determine whether the NDA is complete for filing within 60 days, and the Prescription Drug User Fee Act (PDUFA) target action date will be assigned at that time.
  - Additionally, two manuscripts on the pharmacokinetics of Ryaltris were accepted for publication in the journal *Allergy and Asthma Proceedings*, and Glenmark presented Phase 3 data on Ryaltris at the AAAAI/WAO Joint Congress in March 2018
- GBR 310, the biosimilar candidate for omalizumab (trade name XOLAIR<sup>®</sup>) intended for the treatment of asthma and chronic idiopathic urticaria (CIU), finished a Phase 1 study's last subject, last visit, on April 30, 2018. Topline results are expected in July 2018 and the Company is targeting to initiate a Phase 3 study in H1 CY19.
- GRC 39815 continues to progress well in pre-clinical development

# Ryaltris (mometasone furoate (25 mcg) and olopatadine hydrochloride (665 mcg)) nasal spray suspension (formerly GSP 301)

Ryaltris, an investigational product, is a combination of a steroid and an antihistamine administered intranasally intended for the treatment of seasonal allergic rhinitis. Glenmark reported positive results from a Phase 3 safety trial in perennial allergic rhinitis where Ryaltris demonstrated it was well-tolerated, and the majority of treatment emergent adverse events (TEAEs) were mild-to-moderate in severity. The most frequent TEAEs reported with Ryaltris included nosebleeds (4.6%), headache (4.1%) and a decrease in taste sensitivity (2.0%). In addition, on the secondary efficacy endpoint, treatment with Ryaltris demonstrated statistically significant and clinically meaningful improvement from baseline in average morning patient-reported rTNSS, compared to placebo (p<0.0001) over 52 weeks of treatment.

Glenmark submitted the company's first new drug application (NDA) to the FDA for Ryaltris for the treatment of patients 12 years of age and older with seasonal allergic rhinitis (SAR) on May 21, 2018.

According to the most recent data, over 17 million adults 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.

#### GRC 39815

GRC 39815 is a NCE currently in preclinical studies. It is being evaluated as an inhaled compound for the possible treatment of Chronic Obstructive Pulmonary Disorder (COPD). It is an inhibitor of the Retinoid-related Orphan Receptor gamma t (ROR  $\gamma$  t).



Based on the most recent estimates COPD affects approximately 64 million people worldwide. COPD is an incurable disease and based on the most recent data is the third leading cause of death worldwide.

## GSP 304

GSP 304 is a long-acting muscarinic antagonist administered by nebulization being studied for the long term, once-daily, maintenance treatment of bronchospasm associated with COPD. The GSP 304 program is ongoing and is currently in Phase 2 for patients with mild to moderate COPD as established by the Global Initiative for Chronic Obstructive Lung Disease.

#### GBR 310

GBR 310 is a biosimilar candidate being developed for the treatment of asthma and chronic idiopathic urticaria (CIU). Glenmark has completed a Phase 1 study which will assess the pharmacokinetics of GBR 310 in comparison to the reference product. The trial randomized 168 subjects and 162 completed the study at the end of April, 2018. GBR 310 has the potential to be among the first biosimilar candidates to be submitted to the FDA 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. CIU 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.

#### PAIN ASSET

#### 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.

Glenmark recently announced in January the initiation of a Phase 2b dose finding study in patients with moderate osteoarthritic pain. The Phase 2 study has been initiated in India and planned to enrol 624 patients with osteoarthritis of the knee and hip to evaluate the safety, efficacy and biomarkers associated with GRC 27864 compared to existing NSAID and selective COX-2 inhibitors.

Non-core assets include GRC 17536, GBR 900 and GBR 500. These 3 molecules and GRC 27864 are candidates for out-licensing.

#### **Licensing Updates**

#### India

Glenmark executed the following licensing agreements during FY18

• The Company in-licensed the biosimilar of Adalimumab from Cadila Healthcare Ltd.



- The Company exclusively in-licensed Nourkrin® Woman from Pharma Medico
- The Company exclusively in-licensed AKYNZEO<sup>®</sup> (containing netupitant 300mg and palonosetron 0.5mg) from Helsinn

## US

Glenmark executed the following licensing agreements during FY18

- The Company entered in to an exclusive agreement with Cyndea Pharma S.L. for Generic Soft-Gelatin Capsule Drug Products
- The Company entered in to an exclusive agreement with Sam Chun Dang Pharm. Co. Ltd. (SCD), to develop, manufacture and market a portfolio of ophthalmic products

Glenmark also incurred milestone payments for the following deals during FY18

• Development milestone to Evestra Inc. for the ongoing development of Generic NuvaRing®

#### EU

Glenmark incurred milestone payments for the following deals during FY18

- Approval milestone to Celon Pharma for the development of Generic Seretide Accuhaler<sup>®</sup> - based on first approval received in Nordic Countries
- The Company entered in to an exclusive licensing agreement with a leading European company for a generic inhaler

Glenmark executed the following licensing agreements during FY18

Molecule	For Country			
Femarelle Food Supplement OTC	UK			
Washdent Food supplement OTC	UK			
Febuxostat	DE and ES			
Erlotinib	RO			
Atomoxetine	DE, UK, NL, SE, DK, CZ, SK, PL			
Marimer range extensions	PL			
Bendamustine	ES			
Gefitinib	DE, UK, NL, SE, DK, CZ, PL, RO			
Esomeprazole AOK DE	DE			
Esomeprazole OLS	UK			
Levetiracetam	DE, ES			
Prasugrel	DE			
Abacavir+Lamivudine	ES, NL			
Entecavir extension	CZ, SK			
Dermikelp	UK			
Darunavir	DK, SE, DE, NL, RO, PL			
Fulvestrant	CZ,DE,NL,NO,PL,RO,SK,ES,SE,UK,DK			
Quetiapine SR	DE			
Valganciclovir	DE, UK			
Galantamin	DE			
Posaconazole	DE, UK, NL, DK, SE, RO, CZ, SK			
Ranolazine	DE, UK			
Tenofovir+Emtricitabine+Efavirenz	DE, UK, NL, ES, DK, SE			



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