

**Press Release** 

For Immediate Release

# Glenmark's Consolidated Revenue increases by 15.92% to Rs.16012.23 Mn for Q3 FY 13- 14

- Net Profit for the third quarter was Rs.2162.36 Mn as compared to Rs.2129.17 Mn for the previous corresponding quarter
  - Net profit for the quarter is not comparable due to out-licensing income of Rs.493.03 million received in the previous corresponding quarter
- EBIDTA excluding out-licencing income grew by 34.75% to Rs. 3649.74 mn

**Mumbai**, January 24, 2014: Glenmark Pharmaceuticals Limited (GPL), the research-led global integrated pharmaceutical company announced its results for the third quarter ended December 31, 2013.

For the third quarter ended Dec 31, 2013, Glenmark's Consolidated Revenue was at Rs.16012.23 Mn (USD 259.59 Mn) as against Rs.13812.59 Mn (USD 254.45 Mn) an increase of 15.92%.

Revenue from the Generics Business was at Rs.7372.66 Mn (USD 119.26 Mn) as against Rs.5911.09 Mn (USD 108.99 Mn), growth of 24.73%. The Specialty Formulation Business excluding out-licensing revenue was at Rs.8639.57 Mn (USD 140.33 Mn) as against Rs.7408.47 Mn (USD 136.44Mn) for the corresponding previous quarter, recording a growth of 16.62%.

Net Profit (after taxes and minority interests) for the third quarter was Rs.2162.36 Mn as compared to Rs.2129.17 Mn for the previous corresponding quarter. The Net profit for the quarter is not comparable due to out-licensing income of Rs.493.03 million received in the previous corresponding quarter i.e. Q3 FY 2012-13. EBIDTA excluding out-licencing income grew by 34.75 % to Rs.3649.74

"Despite challenges in the operating environment, we have registered good growth in both our Speciality and Generics Businesses across the globe. We are reasonably confident of maintaining our growth trajectory with our emerging markets businesses being a key growth driver going ahead," said Glenn Saldanha, Chairman & MD – Glenmark. "Our Innovation R&D Business has also been making steady progress with our 4 NCE and 3 NBE molecules at various stages of clinical development," he added.

For the nine month ended Dec 31, 2013, Glenmark's consolidated revenue was at Rs.43021.11 Mn (USD 717.02 Mn) as against Rs.36768.57 Mn (USD 672.92 Mn), an increase of 17.01%. Revenue from the Generics Business was at Rs.20746.85 Mn (USD 345.78 Mn), as against Rs.17030.06 Mn (USD 311.68 Mn), a growth of 21.82 %. The Speciality Formulation Business revenue (excluding out-licensing

revenue) was Rs.22156.16 Mn (USD 369.27 Mn) as against Rs.19245.48 (USD 352.22) for the corresponding previous nine month period, recording a growth of 15.12%.

Net Profit for nine months ended December 31, 2013 was Rs.5021.89 Mn as compared to Rs.4531.65 Mn in the previous corresponding nine months period.

#### **Specialty Business:**

Sales for the Formulation Business in India for the third quarter ended Dec 31, 2013, was at Rs.3812.30 Mn (USD 61.52 Mn) as against Rs.3307.33 Mn (USD 60.98 Mn) in the previous corresponding quarter, recording a growth of 15.27%. For the third quarter, revenue from Africa, Asia and CIS region was as against Rs.3009.60 Mn (USD 49.23Mn) as against Rs.2619.50 Mn (USD 48.18 Mn) for the previous corresponding quarter, recording an increase of 14.89%. Glenmark's revenue from its Latin American and Caribbean operations was at Rs.1139.31 Mn (USD 18.49 Mn) for the third quarter ended Dec31, 2013 as against Rs.1014.69 Mn (USD 18.69 Mn) an increase of 12.28%.

#### **Generics Business:**

Glenmark Generics Inc., U.S.A. registered revenue from sale of finished dosage formulations was Rs.5213.60 Mn (USD 85.00 Mn) for the quarter ended Dec 31, 2013 against revenue of 4365.25 Mn (USD 80.48Mn) for the previous corresponding quarter, recording an increase of 19.43 % . Revenue from the European Formulations Business was Rs.679.99 Mn (USD11.07 Mn) against revenue of Rs.395.16 Mn (USD 7.28 Mn) in Q3 last year, reflecting an increase of 72.08 %. Revenue from sale of API to regulated and semi-regulated markets globally was Rs.1479.07Mn (USD 24.02Mn), for the quarter ended Dec 31, 2013 against Rs.1150.68Mn (USD 21.23 Mn) for the previous corresponding quarter, recording an increase of 28.54%.

#### About Glenmark

Glenmark Pharmaceuticals Ltd. (GPL) is a research-driven, global, integrated pharmaceutical company headquartered at Mumbai, India. It is ranked among the top 80 Pharma & Biotech companies of the world in terms of revenues. (SCRIP 100 Rankings published in the year 2013). 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 primarily focused in the areas of Inflammation [asthma/COPD, rheumatoid arthritis etc.] and Pain [neuropathic pain and inflammatory pain].

The company has a significant presence in branded generics markets across emerging economies including India. GPL along with its subsidiary has 14 manufacturing facilities in four countries and has six R&D centers. Its subsidiary, Glenmark Generics Limited services the requirements of the US and Western Europe generics markets. The API business sells its products in over 80 countries, including the US, various countries in the EU, South America and India.

For further information, please contact: Jason D'Souza / Rajdeep Barooah Glenmark, Mumbai, India Tel: [+91 22] 40189919/984 Email : corpcomm@glenmarkpharma.com



Glenmark Pharmaceuticals Limited PART I

PART II

	Statement of Unaudited financial results for the quarter and Nin-	e months ended 31 December 2013 Standalone (Indian GAAP)				(Rs.in Millions) Consolidated (IFRS )							
	Particulars	Quarter ended 31/12/2013 (Unaudited)	Quarter ended 30/09/2013 (Unaudited)	Quarter ended 31/12/2012 (Unaudited)	Nine months ended 31/12/2013 (Unaudited)	Nine months ended 31/12/2012 (Unsudited)	Year ended 31/03/2013 (Audited)	Quarter ended 31/12/2013 (Unaudited)	Quarter ended 30/09/2013 (Unaudited)	Quarter ended 31/12/2012 (Unaudited)	Nine months ended 31/12/2013 (Unaudited)	Nine months ended 31/12/2012 (Unaudited)	Year ended 31/03/2013 (Audited)
1.	Income from Operations (a) Net Sales / Income from Operations (Net of excise duty)	5,303.18	5,830.26	5,348.91	16,213.2.2	14,511.52	19,352.88	16,012.23	14,630.06	13,812.59	43,021.11	36,768.57	50,123.42
	(b) Other Operating Income	16.14	23.47	76.54	54.17	129.39	140.16	5.29	3.74	- 3.54	12.64	10.04	13.80
	Total Income from Operations (net)	5,319.32	5,853.73	5,425.45	16,267.39	14,640.91	19,493.04	16,017.52	14,633.80	13,816.13	43,033.75	36,778.61	50,137.22
2.	Expenses a. Cost of Materials consumed	1,047.28	1,025.76	1,067.01	3,292.53	3,123.80	4,157.50	3,427.04	4,027.28	4,381.71	11,051.15	11,076.44	12,782.23
	b. Purchase of Stock-in-trade	398.73	338.39	467.74	1,120.22	1,064.90	1,410.88	1,362.10	1,167.62	1,101.46	3,325.80	2,907.26	3,922.20
	c. Changes in Inventories of finished goods, work-in-progress and stock-in-trade	23.58	109.07	7.89	(68.47)	(57.10)	(36.67)	583.95	(326.32)	(806.01)	(85.40)	(1,217.68)	(168.41
	d. Employee benefits expense	1,053.01	1,142.63	793.10	2,926.79	2,288.12	3,030.17	2,734.66	2,644.70	2,123.74	7,487.55	5,794.99	7,882.38
	e. Depreciation and Amortisation expense	80.47	70.51	63.06	217.70	186.14	250.41	611.01	605.24	356.39	1,564.99	952.03	1,270.09
	f. Other expenses	2,034.04	2,114.38	1,993.11	5,795.95	5,478.16	7,606.72	4,260.03	3,963.71	3,813.61	11,970.28	10,651.47	15,605.14
	Total expenses	4,637.11	4,800.74	4,391.91	13,284.7.2	12,084.02	16,419.01	12,978.79	12,082.23	10,970.90	35,314.37	30,164.51	41,293.63
3.	Profit from Operations before Other Income, finance costs & exceptional Items (1-2)	682.21	1,052.99	1,033.54	2,982.67	2,556.89	3,074.03	3,038.73	2,551.57	2,845.23	7,719.38	6,614.10	8,843.59
4.	Other Income	112.34	206.53	133.96	540.43	896.65	1,162.45	50.80	134.04	51.51	218.20	143.26	93.67
5.	Profit from ordinary activities before finance costs and exceptional items ( $3\!+\!4$ )	794.55	1,259.52	1,167.50	3,523.10	3,453.54	4,236.48	3,089.53	2,685.61	2,896.74	7,937.58	6,757.36	8,937.26
6.	Finance costs	83.59	60.53	113.13	237.39	373.62	436.94	472.71	484.57	399.92	1,421.68	1,164.21	1,600.11
7.	Profit from ordinary activities after finance costs but before . Exceptional Items ( 5-6 )	710.96	1,198.99	1,054.37	3,285.71	3,079.92	3,799.54	2,616.82	2,201.04	2,496.82	6,515.90	5,593.15	7,337.15
8.	Exceptional items		-	· .				- 1	· -	-			
9.	Profit from Ordinary Activities before tax (7-8)	710.96	1,198.99	1,054.37	3,285.71	3,079.92	3,799.54	2,616.82	2,201.04	2,496.82	6,515.90	5,593.15	7,337.15
10.	Tax Expense	126.87	139.51	(35.99)	464.15	68.04	(61.53)	473.51	628.01	366.34	1,494.01	1,061.50	1,107.15
11.	Net Profit from Ordinary Activities after tax (9-10)	584.09	1,059.48	1,090.36	2,821.56	3,011.88	3,861.07	2,143.31	1,573.03	2,130.48	5,021.89	4,531.65	6,230.00
12.	Extraordinary items							-					
13.	Net Profit for the period (11-12)	584.09	1,059.48	1,090.36	2,821.50	3,011.88	3,861.07	2,143.31	1,573.03	2,130.48	5,021.89	4,531.65	6,230.00
14.	Share of profit/(loss) of associates										-		
15.	Minority Interest		-					(19.05)	30.06	1.31	29.80	52.21	82.57
16.	Net Profit after taxes, minority interest and share of profit/(loss) of associates (13-14-15)	584.09	1,059.48	1,090.36	2,821.50	3,011.88	3,861.07	2,162.36	1,542.97	2,129.17	4,992.09	4,479.44	6,147.43
17.	Paid-up Equity Share Capital (Face value per share Re. 1)	271.12	271.01	270.74	271.12	270.74	270.85	271.12	271.01	270.74	271.12	270.74	270.85
18.	Reserves excluding Revaluation reserves as per Balance sheet of previous accounting year	-	-				24,960.93						27,359.40
19.i	Earning Per Share (before extraordinary items) (of Re. 1/- caci) (not ammunified ) Basic Earnings Per Share (in Rs.) Diluted Earnings Per Share (in Rs.)	2.15 2.15	3.91 3.91	4.03 4.02	10.41 10.40	11.13 11.12	14.26 14.25	7.98 7.97	5.69 5.69	7.86 7.86	18.42 18.41	16.55 16.53	22.71 22.69
	Earning Per Share (after extraordinary items) (of Re 1/- each) (mot annualised ) Basic Earnings Per Share (in Rs.) Diluted Earnings Per Share (in Rs.)	2.15	3.91 3.91	4.03 4.02	10.41 10.40	11.13 11.12	14.26 14.25	7.98 7.97	5.69 5.69	7.86 7.86	18.42 18.41	16.55 16.53	22.71 22.69

Select information for the quarter and Nine months ended 31 De ember 2013 Nine month Nine months Quarter ended 31/12/2013 Nine months ended 31/12/2013 Nine months ended 31/12/2012 Quarter ended 31/12/2013 Quarter ended 30/09/2013 Quarter ended 31/12/2012 Year ended 31/03/2013 Quarter ender 30/09/2013 Quarter ended 31/12/2012 Particulars Year ended 31/03/2013 ended 31/12/2013 ended 31/12/2012 A Particulars of Shareholding 1. Public Shareholding Number of Shares Percentage of Shareholding 140,169,330 51.70 140,079,730 51.69 139,907,854 51.68 140,169,330 51.70 139,907,854 51.68 140,014,454 51.69 140,169,336 140,079,736 51.69 139.907.854 140,169,336 51.70 139,907,854 51.68 140,014,454 51.69 51.70 51.68 Promoters and promoter group Shareboking a) Ploaged/Encumbered Number of shares - Varenettage of shares (as a % of the total sharehoking of promoter and promoter group) - Precentage of shares (as a % of the total share capital of the company) b) Non-encumbered - Number of Shares (as a % of the total sharehoking of promoter and promoter group) - Precentage of shares (as a % of the total sharehoking of promoter and promoter group) - Precentage of shares (as a % of the total share capital of the company) Nil Nil Nil Nil Nil Nil Nil Nil N il N il Nil 130,955,617 100.00 130,830,199 100.00 130,955,617 130,925,617 100.00 130,830,199 100.00 130,955,617 100.00 130,830,199 100.00 130,839,199 100.00 130,955,613 130,925,617 100.00 130,830,199 130,839,199 100.00 100.00 100.00 48.30 48.31 48.32 48.30 48.32 48.31 48.30 48.31 48.32 48.30 48.32 48.31 company)



Glenmark Pharmaceuticals Ltd.

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	Particulars	Quarter ended 31/12/2013	
В	Investors complaints		
	Pending at the beginning of the quarter		
	Received during the quarter	12	
	Disposed off during the quarter	12	
	Remaining unresolved at the end of the quarter		

#### Notes:

 Water

 1
 The above results were reviewed by the Audit Committee and approved at the meeting of the Board of Directors held on January 24,2014.

 1
 The Company is exclusively in the Pharmaceutical business segment.

 0
 During the quarter ended December 31, 2013, pursuant to Employee Stock Option Scheme 2003, the Company converted 119,600 options into equivily shares of Re.1 each. As at December 31, 2013, 482,500 options were outstanding, which upon exercise are convertible into equivily shares of Re.1 each. As at December 31, 2013, 482,500 options were outstanding, which upon exercise are convertible into equivily shares.

cquivalent number of equips suares.
 Tax expenses is computed after considering MAT credit and other income tax benefits.
 5 Diluted ES has been computed considering the effect of conversion of ESOPs.
 6 The Standalone Financial Statements have been prepared in accordance with accounting principles generally accepted in India including the Accounting Standards notified under the Companies (Accounting Standards )Rules, 2006 (as amended).

7 The Company has voluntarily adopted IFRS (International Financial Reporting Standards) in preparation of the consolidated financial statements as per the requirements of SEBI circular dated April 5, 2010, accordingly the consolidated results have been prepared in accordance with the recognition and measurement principles as per IFRS and presented in the format as per clause 41 of the listing agreement.

8 Previous period's figures have been re-grouped/re-classified wherever necessary.

For and on behalf of the Board of Directors 1 £

# Glenn Saldanha Chairman & Managing Director

Mumbai, 24 January, 2014



# Management Discussion and Analysis for the Third quarter of FY 2013-14 Revenue Figures – Consolidated

#### INR in Millions

	Third q	uarter ended D	ec 31	Nine months ended Dec 31			
	FY 2013-14	FY 2012-13	Growth %	FY 2013-14	FY 2012-13	Growth %	
Specialty Business							
India	3812.30	3307.33	15.27	11274.93	9545.47	18.12	
Rest of the World (ROW)	3009.60	2619.50	14.89	6431.03	5908.90	8.84	
Latin America	1139.31	1014.69	12.28	2983.80	2675.18	11.54	
Europe	678.36	466.95	45.27	1466.40	1115.93	31.41	
Total	8639.57	7408.47	16.62	22156.16	19245.48	15.12	
Out-Licensing Revenue	-	493.03	-100.00	118.10	493.03	-76.05	
Total Specialty Business	8639.57	7901.50	9.34	22274.26	19738.51	12.85	
Generics Business							
US	5213.60	4365.25	19.43	15261.72	12596.04	21.16	
Europe	679.99	395.16	72.08	1662.30	1115.97	48.96	
API	1479.07	1150.68	28.54	3822.83	3318.05	15.21	
Total Generics Business	7372.66	5911.09	24.73	20746.85	17030.06	21.82	
Consolidated Revenue	16012.23	13812.59	15.92	43021.11	36768.57	17.01	

Average conversion rate in 9M FY 2013-14 considered is Rs. 60.00 / USD 1.00

Average conversion rate for 9M FY 2012-13 considered is Rs54.64 / USD 1.00

USD figures are only indicative



#### Review of Operations for the quarter ended Dec 31, 2013

For the third quarter ended Dec 31, 2013, Glenmark's consolidated revenue was at Rs. 16012.23 Mn (USD 259.59 Mn ) as against Rs. 13812.59 Mn (USD 254.45 Mn) an increase of 15.92%.

Revenue from the generics business was at Rs 7372.66 Mn (USD 119.26 Mn) as against Rs. 5911.09 Mn (USD 108.99 Mn), growth of 24.73 %. The Specialty formulation business excluding out-licensing revenue was at Rs. 8639.57 Mn (USD 140.33 Mn) as against Rs. 7408.47 Mn (USD 136.44 Mn) for the corresponding previous quarter, recording a growth of 16.62 %.

#### **Specialty Business:**

#### India

Sales for the formulation business in India for the third quarter ended Dec 31, 2013, was at Rs. 3812.30 Mn [USD 61.52 Mn] as against Rs. 3307.33 Mn [USD 60.98 Mn] in the previous corresponding quarter, recording a growth of 15.27 %.

As per ORG IMS Mat Dec 2013, Glenmark Pharmaceuticals (IF) gained 2 ranks from 21<sup>st</sup> to 19<sup>th</sup> as compared to MAT Dec 2012 with increase in market share to 2.09 % exhibiting value growth of 15.6 % vis-a-vis IPM growth of 10.06%.

The India business strengthened its presence in following therapeutic segments with growth in market share as per ORG Mat Dec 12' v/s Mat Dec 13' respectively. The cardiac segment increased market share from 3.27% to 3.49%. The respiratory division increased market share from 3.21% to 3.47 %. The anti-infective segment increased market share from 1.48 % to 1.62 %. The gynaecology division increased market share from 1.33% to 1.50%. The derma segment market share was 8.75% to 8.16 % and the Anti-diabetic division market share increased from 1.30% to 1.47%.

## Africa, Asia and CIS Region (ROW)

For the third quarter, revenue from Africa, Asia and CIS region was Rs. 3009.60 Mn [USD 49.23 Mn] as against Rs. 2619.50 Mn [USD 48.18 Mn] for the previous corresponding quarter, recording an increase of 14.89%.



The secondary sales for the Russian subsidiary showed good growth in the third quarter. The IMS MAT November'13 data shows that Glenmark Russia recorded growth of 29% in value vs overall market growth of 10.4%. In the Respiratory segment Glenmark grew by 18.7 % vs overall respiratory market growth of 12.3 %. The MAT November'13 data showed that the Dermatology segment for Glenmark grew by 57.1 % in value vs overall dermatology market growth of 17.8%. Glenmark's rank improved to 50 in MAT November'13 from rank 55 in MAT November'12. Glenmark Ukraine subsidiary as per MAT November'13 showed that it grew by 83% in value vs overall market growth of 14.6% in value. Glenmark Ukraine's market rank has gone up to 82 in MAT November 2013, from 116 in MAT November 2012.

The Africa/Middle East region posted good secondary sales growth in the third quarter. All subsidiaries in the region recorded good growth. The Asia region rebounded strongly and grew 27 % in secondary sales for the third quarter. Glenmark's subsidiaries in Philippines, and Myanmar grew by 37 % & 35 % respectively in the third quarter. The Philippines subsidiary received approval for Generic Seretide in the quarter.

#### Latin America

Glenmark's revenue from its Latin American and Caribbean operations was at Rs. 1139.31 Mn [USD 18.49 Mn] for the third quarter ended Dec 31, 2013 as against Rs. 1014.69 Mn [USD 18.69 Mn] an increase of 12.28 %.

The Mexico, Venezuela and the Caribbean subsidiary performed well recording good growth during the quarter while the Brazil subsidiary recorded moderate growth. The Brazil subsidiary launched two new products in the dermatology range. The Mexico subsidiary received approval for Generic Seretide. This is the first generic approved in the market and the subsidiary will launch the product in the fourth quarter.

## **Central Eastern Europe**

Glenmark Europe's operations revenue for the third quarter ended Dec 31, 2013 was at Rs. 678.36 Mn [USD 11.09 Mn] as against Rs. 466.95 Mn [USD 8.59 Mn] recording growth of 45.27 % .

The Central Eastern Europe region performed well during the quarter with all the subsidiaries registering strong growth. The Czech subsidiary launched 6 new products; the Polish subsidiary launched 2 new products and the Romania subsidiary launched 5 new products. Glenmark succeeded in a Day one launch of Capecitabine in Czech, Slovakia and Romania. Also temozolomide and zolendronic acid have been launched in



Poland, in addition to all other countries in the region. The growth of Q3 is the combination of new launches with high effectiveness of sales and marketing activities coupled with disciplined P&L and cash management.

#### **Generics Business:**

#### **USA Formulations**

Glenmark Generics Inc., U.S.A. registered revenue from sale of finished dosage formulations was Rs. 5213.60 Mn (USD 85.00 Mn) for the quarter ended Dec 31, 2013 against revenue of 4365.25 Mn (USD 80.48 Mn) for the previous corresponding quarter, recording an increase of 19.43 %.

In the third quarter of fiscal year 2014, Glenmark was granted a tentative approval for Desmopressin Tablets. The Company filed three ANDA's with the U.S. FDA taking the total tally for the year to twelve. The company plans to file another 8 to 10 applications in the forthcoming quarter.

Glenmark's marketing portfolio through December 31, 2013 consists of 90 generic products authorized for distribution in the U.S. market. The Company currently has 59 applications pending in various stages of the approval process with the US FDA, of which 29 are Paragraph IV applications.

## **EU Formulations**

The European business continued expanding through product sales and licensing income and by enhancing its presence through distribution partners in European countries. The business launched three inhouse products in Germany and three products in the UK comprising of two in-licensed products and one inhouse product. In the Nordic markets, there was a launch of one more inhouse product. Through products licensed out to partners, we also launched three additional products in several European Markets. The Netherlands and the Germany entity continued supplying products through the existing and new health insurance contracts. The out-licensing business successfully signed one new deal and marketing authorisations for seven different products in different countries were also received this quarter.

Revenue for the quarter was Rs. 679.99 Mn (USD 11.07 Mn) against revenue of Rs. 395.16 Mn (USD 7.28 Mn) in Q3 last year, reflecting an increase of 72.08 %.



#### Active Pharmaceutical Ingredients [API]

Revenue from sale of API to regulated and semi-regulated markets globally was Rs. 1479.07 Mn [USD 24.02 Mn] ), for the quarter ended Dec 31, 2013 against Rs. 1150.68 Mn [USD 21.23 Mn] for the previous corresponding quarter, recording an increase of 28.54 %. The API facility in Ankleshwar successfully completed a COFEPRIS inspection. We have filed 4 new DMFs in this financial year and acceptable audit status has been maintained for our facilities.

#### **Research & Development**

The company has a pipeline of 4 NCE and 3 NBE molecules in clinical trials or ready to enter clinical trials soon, including the in-licensed molecule "Crofelemer".

## GRC 17536

GRC 17536, a TRPA1 antagonist, has proven highly efficacious in treating inflammatory and neuropathic pain in animal models. In addition, when tested in in-vivo model of asthma, it showed promising effect on airway inflammation, bronchoconstriction and cough. GRC 17536 has showed good safety in the Phase 1 enabling GLP safety pharmacology and toxicology studies performed. Glenmark has completed Phase 1 study in the Netherlands. Single and multiple ascending doses have been well tolerated with expected pharmacokinetic profile.

Glenmark is currently recruiting patients for a Phase II proof of concept study in pain indication in Europe and India.

Additionally, Glenmark has completed recruitment for a Phase I/IIa study for respiratory indications in the UK (MHRA). Topline data shows that inhaled doses of GRC 17536, upto maximum dose tested, were well tolerated in mild asthmatics. Final TFLs for the study are awaited. Glenmark has initiated recruitment for a Phase IIa study in patients with chronic cough.



#### GRC 15300

GRC 15300, a TRPV3 inhibitor for Neuropathic pain, Osteoarthritic pain and other inflammatory pain has completed Phase 1 trials in the UK. Globally, this is the only reported TRPV3 specific antagonist molecule to enter clinical trials. A development and commercialisation license for GRC 15300 has been granted to Sanofi. A PhIIa proof of concept study in neuropathic pain has completed recruitment and trials are ongoing.

#### mPGES-1 inhibitors

Glenmark has entered into an option agreement with Forest Laboratories, Inc on a collaboration for the development of novel mPGES-1 inhibitors to treat chronic inflammatory conditions, including pain. Glenmark has identified clinical candidates and is currently conducting pre-clinical studies and other development activities required to support the initiation of first-in-human dosing. Forest has an exclusive option to obtain license rights to the program upon the completion of Phase 1 clinical trials. Phase 1 enabling toxicity studies have been initiated for a lead candidate.

#### Vatelizumab (GBR 500):

GBR 500, a monoclonal antibody, is an antagonist of the VLA-2 (alpha2-beta1) integrin. It has the potential to be a broadly applicable anti-inflammatory compound in diseases like Crohn's disease (CD) and Multiple Sclerosis. It is a "first in class" monoclonal antibody therapeutic with this target and has established proof of concept in animals. Phase I studies for GBR 500 have been completed in the US. GBR 500 has been licensed to Sanofi. A PhII proof of concept study in ulcerative colitis has been initiated and is currently ongoing.

#### GBR 900:

Glenmark licensed from Lay Line Genomics, Italy, exclusive intellectual property rights for monoclonal antibodies against the neuronal growth factor receptor TrkA. TrkA is part of the NGF-TrkA axis, a validated and novel pain receptor system for treatment of chronic pain. Pre-clinical research on the GBR 900 project is being carried out at Glenmark's Biologics Research (GBR) centre at La Chaux-de-Fonds, Switzerland and is progressing well. Phase 1 enabling toxicity studies for GBR 900 have been completed successfully. Glenmark plans to file for a Phase I study in the current financial year.

#### GBR 830

GBR 830, the first anti-OX40 monoclonal antibody was discovered at the Glenmark Biologics Research Centre located in Switzerland. The development of OX40 antagonists



has been very challenging and Glenmark has achieved a significant milestone with the successful generation of an antagonistic OX40 monoclonal antibody coupled with generation of data validating the role of OX40 in autoimmune diseases. GBR 830 shows great promise to emerge as a valuable therapeutic option to treat patients suffering from autoimmune diseases. Phase 1 enabling toxicity studies for GBR 830 have been completed and Glenmark plans to file for a Phase 1 study in FY 2015.

#### Crofelemer

Salix Pharmaceuticals, Inc has launched Crofelemer in the US after obtaining marketing authorization from the US FDA on 31<sup>st</sup> December 2012. Crofelemer is approved in the US for symptomatic relief of non-infectious diarrhoea in patients with HIV/AIDS on antiretro viral therapy. The US approval and launch of Crofelemer significantly aids the Glenmark filings within the 140 Countries where it has exclusive marketing and distribution rights.

The Dec 2012 approval of Crofelemer by the US FDA for Salix Pharmaceuticals, Inc. will help support the filing and approval of Crofelemer in the 140 Countries where Glenmark has exclusive marketing and distribution rights. In CY 2013, filings in some key markets have been made and filings in several additional markets are planned in CY 2014. The recruitment in the pivotal C-Forward trial in adult acute watery diarrhoea is progressing well and results of the trial are expected in FY 2015. In addition Glenmark has also submitted the protocol of a Proof-Of-Concept Pediatric clinical trial for acute watery diarrhoea with approval for trial start expected to commence in the next few months.

#### Disclaimer

This document has been prepared by Glenmark Pharmaceuticals Ltd. The information, statements and analysis made in this document describing company's objectives, projections and estimates are forward looking statements and progressive within the meaning of applicable Security Laws and Regulations. The analysis contained herein is based on numerous assumptions. Actual results may vary from those expressed or implied depending upon economic conditions, government policies and other incidental factors. No representation or warranty, either expressed or implied, is provided in relation to this presentation. This presentation should not be regarded by recipients as a substitute for the exercise of their own judgment.

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#### **Review Report**

#### To the Board of Directors of Glenmark Pharmaceuticals Limited

- 1. We have reviewed the accompanying statement of unaudited standalone (Indian GAAP) financial results ("the Statement") of Glenmark Pharmaceuticals Limited ("the Company") for the quarter ended 31 December 2013 and the year to date results for the period 1 April 2013 to 31 December 2013, except for the disclosures regarding Public Shareholding' and Promoter and Promoter Group Shareholding' which have been traced from disclosures made by the management and have not been audited by us. This Statement is the responsibility of the Company's Management and has been approved by the Board of Directors. Our responsibility is to issue a report on the Statement based on our review.
- 2. We conducted our review in accordance with the Standard on Review Engagements (SRE) 2410, Review of Interim Financial Information Performed by the Independent Auditor of the Entity, issued by the Institute of Chartered Accountants of India. This standard requires that we plan and perform the review to obtain moderate assurance as to whether the Statement is free of material misstatement. A review is limited primarily to inquiries of company personnel and analytical procedures, applied to financial data and thus provides less assurance than an audit. We have not performed an audit and accordingly, we do not express an audit opinion.
- 3. Based on our review conducted as above, nothing has come to our attention that causes us to believe that the accompanying Statement prepared in accordance with applicable accounting standards, as notified under the Companies (Accounting Standards) Rules, 2006 (as amended) and other recognised accounting practices and policies has not disclosed the information required to be disclosed in terms of Clause 41 of the Listing Agreement, including the manner in which it is to be disclosed, or that it contains any material misstatement.

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For Walker, Chandiok & Co Chartered Accountants Firm Registration/No: 0010761

per Ashish Gupta Partner Membership No.: 504662

Mumbai 24 January 2014

#### **Chartered Accountants**