

January 3, 2024

To,
Dy. General Manager
Department of Corporate Services,
BSE Ltd.
Phiroze Jeejeebhoy Towers
Dalal Street, Fort, Mumbai – 400 001

To,
The Manager – Listing,
The National Stock Exchange of India Ltd.,
Plot No. C/1, G Block
Bandra Kurla Complex,
Bandra (E), Mumbai – 400 051

Ref: Scrip Code: 532296

Ref: Scrip Name: GLENMARK

Dear Sir,

Sub: Glenmark is the first to launch Biosimilar of Popular Anti-Diabetic Drug, Liraglutide, in India

With reference to the subject mentioned above, kindly find attached media release which is self-explanatory.

Request you to kindly take the same on record.

Thanking you,

Yours faithfully,
For Glenmark Pharmaceuticals Limited

Harish Kuber
Company Secretary & Compliance Officer

Encl: As above

Press Release

For immediate distribution

Glenmark is the first to launch Biosimilar of Popular Anti-Diabetic Drug, Liraglutide, in India

- *The anti-diabetic biosimilar has been launched under the brand name Lirafit™, and is indicated for improving glycemic control in adult patients with type 2 diabetes mellitus.¹*
- *Clinical trials on Liraglutide have demonstrated several benefits, including effectively lowering glycemic parameters, weight reduction, and cardiovascular safety in patients with type 2 diabetes mellitus.^{2,3,4,5}*
- *Liraglutide belongs to the class of glucagon-like peptide 1 receptor agonists (GLP-1 RAs) that are recommended in the treatment guidelines by the American Diabetes Association as well as the American Association of Clinical Endocrinology (AACE) Consensus Statement & European Society of Cardiology for type 2 diabetes mellitus patients with co-morbidities, like established atherosclerotic cardiovascular disease and obesity.^{6,7,8,9}*
- *Lirafit™ will sharply lower the daily cost of therapy by around 70% to around INR 100; making the drug more accessible to a larger number of patients with type 2 diabetes mellitus in the country.*

Mumbai, India, 03 January 2024: Glenmark Pharmaceuticals Ltd. (Glenmark), a research-led, global pharmaceutical company, has launched a biosimilar of the popular^{10,11} anti-diabetic drug, Liraglutide, for the first time in India. The drug is being marketed under the brand name Lirafit™ following the approval from the Drug Controller General of India (DCGI). Priced at around INR 100 for a standard dose of 1.2 mg (per day), this will lower the cost of therapy by approximately 70%, and will be available only under prescription.

Liraglutide belongs to the class of glucagon-like peptide 1 receptor agonist (GLP-1 RA) drugs, which increase glucose-dependent insulin secretion and decrease in appropriate glucagon secretion.^{12,13} It has been approved globally for the management of type 2 diabetes mellitus in adult patients in the United States and the European Union.¹⁴

“Glenmark is proud to introduce Lirafit™, a novel and affordable biosimilar of the drug liraglutide, for the first time in India. Clinical trials have shown that it helps improve glycemic control in adult type 2 diabetes mellitus patients along with atherosclerotic cardiovascular diseases (ASCVD) and obesity.¹⁻⁵ Liraglutide has also proven to have a positive impact on cardiac and renal safety outcomes among patients in clinical trials, making it an effective choice of treatment for patients with type 2 diabetes mellitus.^{4,5,7,14,15} With this launch, we have now ventured into the injectable anti-diabetic market taking another significant stride in the diabetes therapy space,” remarked Alok Malik, President and Business Head - India Formulations, Glenmark Pharmaceuticals Ltd.

Liraglutide and its role in the treatment of type 2 diabetes

Liraglutide has a proven efficacy in improving glycemic control in patients with type 2 diabetes mellitus. Clinical trials on Indian adult patients with type 2 diabetes mellitus over a 24-week period have demonstrated Lirafit™ to be effective, safe and well-tolerated. The trials also revealed non-inferior efficacy and a safety profile with that of the reference liraglutide.¹⁶ Additional benefits of liraglutide include effectively lowering glycemic parameters, weight reduction, and cardiovascular safety in patients with type 2 diabetes mellitus^{2-5,13,14}.

GLP-1 RA class of drugs and their mechanism of action

GLP-1 RA (Glucagon-like peptide-1 receptor agonists) are a group of drugs used in the treatment of type 2 diabetes.¹³ GLP-1 RAs are very effective in lowering blood sugar levels. Several trials have demonstrated that GLP-1 RAs reduce cardiovascular risk in patients with type 2 diabetes mellitus and ASCVD or high cardiovascular risk and have beneficial effects on cardio-renal outcomes beyond their blood glucose-lowering effects in type 2 diabetes mellitus patients.^{17,18} Their mechanism of action involves the release of insulin, in the presence of elevated glucose concentrations, thus decreasing glucagon secretion.^{12,13} GLP-1 RAs are recommended in the treatment guidelines by the American Diabetes Association as well as the American Association of Clinical Endocrinology (AACE) Consensus Statement & European Society of Cardiology for type 2 diabetes mellitus patients with co-morbidities, like established atherosclerotic cardiovascular disease and obesity.^{6,7,8,9} The American Diabetes Association (ADA) also recommends GLP1RAs therapy for weight loss & lesser risk of hypoglycemia in type 2 diabetes mellitus patients.^{6,7} Drugs belonging to this class include liraglutide, semaglutide, and dulaglutide, among others.

Glenmark's expertise in diabetes management

Glenmark has a strong legacy of bringing in new, effective, and affordable treatment options for diabetic patients, especially for those suffering from uncontrolled Type 2 diabetes. In 2015, Glenmark was the first to launch the DPP4 inhibitor, Tenelegliptin (Zita Plus® and Ziten®), followed by a FDC of Tenelegliptin + Metformin (Zita-Met Plus® and Ziten-M®). Glenmark later introduced Remogliflozin (Remo® and Remozen™), a novel SGLT-2 inhibitor in 2019; and subsequently, its combinations (Remo-V®, Remozen™-V, Remo MV®, and Remozen™ MV). Glenmark followed that up with the launch of Sitagliptin (Sitazit®) and its FDCs in 2022. Then came Lobeplitazone (LOBG®) and additional FDCs of Tenelegliptin, including its combinations with Pioglitazone (Zita Pio™), Pioglitazone + Metformin (Zita®-PioMet), Dapagliflozin (Zita-D™), and Dapagliflozin + Metformin (Zita® DM). Liraglutide (Lirafit®), a glucagon-like peptide-1 receptor agonist (GLP-1 RA) is the latest affordable offering from Glenmark, marking its entry into the injectable anti-diabetic market.

Prevalence of diabetes in India

As per the ICMR-INDIAB study conducted between October 2008 and December 2020, the overall weighted prevalence of diabetes was 11.4%¹⁹. According to IQVIA™ sales data for the 12-month period ending August 2023 (MAT August 2023), the market for GLP-1 RA in India is estimated to be INR 259 crores, with an annual growth of 108% against the corresponding period last year (MAT August 2022).

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About Glenmark Pharmaceuticals Ltd

Glenmark Pharmaceuticals Limited (BSE: 532296 | NSE: GLENMARK) is a research-led, global pharmaceutical company, having a presence across Branded, Generics, and OTC segments; with a focus on therapeutic areas of respiratory, dermatology and oncology. The company has 10 world-class manufacturing facilities spread across 4 continents, and operations in over 80 countries. In Vivo/Scrip 100 positions Glenmark amongst the Top 100 Companies Ranked by R&D and Pharmaceutical Sales, 2022; while Generics Bulletin/In Vivo places it in the Top 50 Generics and Biosimilars Companies Ranked by Sales, 2022. The company has also been Great Place To Work® Certified™ in India for FY 2023. Glenmark's Green House Gas (GHG) emission reduction targets have been approved in 2023 by the Science Based Target initiative (SBTi), making it only the second pharmaceutical company in India to achieve this. The organization has impacted over 2.9 million lives over the last decade through its CSR interventions. For more information, visit www.glenmarkpharma.com. You can follow us on LinkedIn (Glenmark Pharmaceuticals) and Instagram (glenmark_pharma).

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- * HbA1c is the average blood glucose (sugar) levels for the last two to three months
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