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## **Sun Pharma's GL0034 (Utreglutide) Demonstrates Significant Weight Loss, Gluco-metabolic and Lipid Lowering Efficacy in Individuals with Obesity in Oral Presentation at the American Diabetes Association 84th Scientific Sessions**

- *GL0034 administered once-weekly confirmed clinically meaningful weight loss and improved gluco-metabolic parameters over a 4-week treatment period in individuals with obesity, even in the lowest dosing regimen.*
- *GL0034 demonstrated gluco-metabolic activity and reductions in lipid levels, including triglycerides, total cholesterol, and non-HDL cholesterol, suggesting novel and beneficial effects on lipid metabolism.*
- *GL0034 exhibited a favorable tolerability profile, with gastrointestinal (GI) adverse events consistent with those typically observed in the incretin class.*
- *These findings highlight GL0034's potential as a therapeutic option for individuals with obesity, providing not only weight loss but also improvements in key cardiometabolic biomarkers.*

**MUMBAI, India and NEW YORK, June 22, 2024 /PRNewswire/** -- Sun Pharmaceutical Industries Limited (Reuters: SUN.BO, Bloomberg: SUNP IN, NSE: SUNPHARMA, BSE: 524715) (together with its subsidiaries and/or associates referred as "Sun Pharma") announced results from a Phase 1, multiple ascending-dose study evaluating the safety, tolerability, pharmacokinetics, and pharmacodynamics of GL0034 (Utreglutide) in obese adults. The data was exhibited in an oral presentation at the 84th Scientific Sessions of the American Diabetes Association (ADA), on June 21, 2024, in Orlando, FL.

Obesity is a rapidly growing global health concern, contributing to numerous metabolic disorders, including type 2 diabetes mellitus (T2DM), cardiovascular diseases, and metabolic dysfunction-associated steatohepatitis (MASH). Effective treatments are crucial for managing obesity and its associated comorbidities. GLP-1 (glucagon-like peptide-1) receptor agonists have emerged as a promising therapeutic class for obesity.

GL0034 (Utreglutide) is a novel differentiated incretin analogue with potent, long-acting agonist activity at the GLP-1 receptor. This innovative compound is under evaluation for its potential to provide significant clinical benefits beyond weight loss and gluco-metabolic benefits in individuals with obesity.

"The recent GL0034 study has shown encouraging results with significant weight loss and notable improvements in lipid profiles among obese participants," said Richard E. Pratley, MD, Medical Director, AdventHealth Diabetes Institute and Senior Investigator, Diabetes Program Lead, Translational Research Institute. "This investigational therapy stands out as a potentially differentiated asset in the weight management field. The positive outcomes emphasize the potential of this treatment and set the stage for further research and development."

"The promising data from our GL0034 study highlights our commitment to addressing the growing global health challenge of obesity. These findings not only demonstrate the activity of GL0034 in promoting weight loss but also underscore its potential in improving crucial cardiometabolic parameters and risk factors," said Dilip Shanghvi, Managing Director, Sun Pharma. "We are dedicated to advancing this innovative therapy to bring meaningful benefits to patients worldwide."

### **GL0034 Oral Presentation at the ADA 2024 Scientific Sessions**

***Safety, Tolerability, and Metabolic Effects of Once-Weekly GL0034 (Utreglutide) in Individuals with Obesity—A Multiple Ascending Dose Study. [Oral Presentation #121-OR, Friday, June 21, 2024, 05:00pm-5:15pm ET, W415C (Valencia Ballroom), Presented by Dr. Rajamannar Thennati]***

Healthy, obese male participants (n=24; Age 18-40; BMI  $\geq$  28 kg/m<sup>2</sup>) were enrolled into a fixed-dose Cohort 1 (4 x 680  $\mu$ g) or an increasing-dose Cohort 2 (680/900/1520/2000  $\mu$ g) and assigned to treatment groups in a 3:1 ratio, receiving 4 weekly doses of either GL0034 or a placebo. An oral glucose tolerance test (OGTT) was performed on Day -1 (baseline) and Day 23 (after the 4th dose). The results were as follows:

- Significant body weight reduction was observed from baseline at Day 29 and persisted through Day 43 in treatment cohorts compared to placebo.
  - Absolute weight loss change of  $-4.6 \pm 1.5$  (P<0.001) in Cohort 2.
- Both cohorts showed significant reductions in glucose AUC<sub>0-120</sub> min during OGTT on Day 23 and dose-dependent insulin AUC<sub>0-120</sub> min reductions, suggesting improved insulin sensitivity.
- HbA1c, leptin levels, and lipid levels (triglycerides, total cholesterol, non-HDL cholesterol) were reduced in the treatment cohorts.

GL0034 was well-tolerated with no treatment-related discontinuations. The most common adverse events were gastrointestinal, consistent with the incretin class profile.

The study was conducted in Belgium.

The accumulating evidence suggests that GL0034 has a potentially differentiated profile in the evolving landscape of obesity treatment. The Phase 1 study results have demonstrated clinically meaningful weight loss, significant metabolic improvements, and a favorable tolerability profile. Notably, GL0034 has shown a novel ability to lower lipid profiles, especially triglycerides, suggesting an additional therapeutic benefit that sets it apart from other treatments. As a selective GLP-1 receptor agonist, GL0034 shows potential for enhanced therapeutic benefits.

"The significant weight loss and metabolic improvements observed with GL0034 strongly support the further clinical evaluation of this novel GLP-1 receptor agonist for treating obesity, type 2 diabetes, metabolic dysfunction-associated steatohepatitis, and other weight-related comorbidities. To confirm these benefits, we will conduct larger, randomized controlled studies to fully elucidate the therapeutic potential of GL0034 for patients," said Rajamannar Thennati, MD, Lead Investigator and Executive Vice President, Research & Development, Sun Pharma.

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### **About Sun Pharmaceutical Industries Limited (CIN - L24230GJ1993PLC019050)**

Sun Pharma is a leading global specialty generics company with presence in Innovative products, Generics and Consumer Healthcare products. It is the largest pharmaceutical company in India and is a leading generic company in the US as well as Global Emerging Markets. Sun's high growth Global Specialty portfolio spans innovative products in dermatology, ophthalmology, and onco-dermatology and accounts for over 18% of company sales. The company's vertically integrated operations deliver high-quality medicines, trusted by physicians and consumers in over 100 countries. Its manufacturing facilities are spread across six continents. Sun Pharma is proud of its multi-cultural workforce drawn from over 50 nations. For further information, please visit [www.sunpharma.com](http://www.sunpharma.com) and follow us on "X" @SunPharma\_Live.

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