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## **Sun Pharma Presents Data from First-in-Human Phase 1 Studies of GL0034 at the American Diabetes Association 83<sup>rd</sup> Scientific Sessions**

***GL0034 is a novel, investigational glucagon-like peptide 1 receptor agonist (GLP-1RA) being studied for the treatment of type 2 diabetes and obesity***

***GL0034 reduced body weight after a single dose in obese individuals without diabetes***

***Marked dose dependent reductions in body weight seen in multiple-ascending dose study in healthy individuals***

***GL0034 was generally well tolerated in both Phase 1 studies***

***Phase 2 clinical trials anticipated to commence in 2023***

**MUMBAI, India and PRINCETON, N.J., June 24, 2023** – Sun Pharmaceutical Industries Ltd. (Reuters: SUN.BO, Bloomberg: SUNP IN, NSE: SUNPHARMA, BSE: 524715, “Sun Pharma” including its subsidiaries and/or associate companies) today announced results from two Phase 1 studies evaluating the tolerability, safety, pharmacokinetics and pharmacodynamics of GL0034, a novel long-acting GLP-1 receptor agonist, in non-obese and obese adults without diabetes. The data will be highlighted in poster presentations at the American Diabetes Association’s (ADA) 83<sup>rd</sup> Scientific Sessions held from June 23-26, 2023, in San Diego, CA.

In one of the studies, GL0034 reduced triglyceride levels and body weight by Day 8 after a single dose in obese individuals without diabetes. In the other study, GL0034 administered at multiple-ascending doses once weekly for up to 8 weeks was well tolerated and resulted in meaningful pharmacodynamic effects in healthy individuals with normal body weight. In this study, marked dose dependent reductions in body weight of up to -10.7% were observed following GL0034 treatment of relatively low doses for 4 to 8 weeks. Across the two Phase 1 studies, the most common adverse events occurring ( $\geq 5$  participants in any dose arm) included nausea, vomiting, decreased appetite, early satiety, and dyspepsia.

“The results of the Phase 1 trial of GL0034 are promising based on the safety and efficacy profile,” said Richard E. Pratley, MD, Medical Director, AdventHealth Diabetes Institute and Senior

Investigator, Diabetes Program Lead, Translational Research Institute. "GL0034 has a promising future in terms of weight loss and glycemic effects and based on these early results presented at ADA, GL0034 has a potential to be best in class. I look forward to learning more through further studies."

"The rising incidence of obesity and diabetes places significant burden on global healthcare systems, and GLP-1 agonists have emerged as a useful option for treating these conditions with a single agent. We believe the Phase 1 data of Sun's GL0034 potentially differentiates it from approved therapies in its class. We are excited to take the product through to the next stage of development," said Dilip Shanghvi, Managing Director, Sun Pharma.

GL0034 was discovered and is being developed by Sun Pharma. Further clinical studies are planned to confirm clinical safety and efficacy, including a 12-week proof of concept study in obese adults with type 2 diabetes, with non-alcoholic fatty liver (NAFL) and non-alcoholic steatohepatitis (NASH) biomarkers, which will begin enrollment during 2023.

"These Phase 1 studies suggest a potential role for GL0034 as a unique candidate to provide therapeutic benefits for obese adults," said Rajamannar Thennati, MD, Lead Investigator and Executive Vice President, Research & Development, Sun Pharma. "Initial results showed that GL0034 was generally well tolerated, and we are encouraged by the rate and durability of weight loss in these populations and look forward to proceeding to Phase 2 trials in obesity and type 2 diabetes."

### **GL0034 Poster Presentations at the ADA 2023 Scientific Sessions**

#### ***A Single-Ascending Dose Study of The Novel GLP-1 Receptor Agonist GL0034 (Utregrlutide) in Obese Individuals Without Diabetes. [Poster # 765-P, Sunday, June 25, 2023, 11:30am – 12:30pm PT, Hall B-C, Presented by Dr. Rajamannar Thennati]***

- Participants (n=24; BMI  $\geq 30$  kg/m<sup>2</sup>) were randomized 3:1 to treatment with GL0034 or placebo. The cohorts achieved mean percent changes in body weight, ranging from -1.9% at the 2000  $\mu$ g dose (p<0.01) to -2.5% at the highest dose (2520  $\mu$ g; p<0.001) at Day 8 and sustained beyond initial treatment exposure through Day 22, compared to 0.3% at Day 8 and -0.1% at Day 22 in placebo-treated participants.
- Triglyceride levels were significantly decreased from baseline in participants treated with GL0034 2000  $\mu$ g and 2520  $\mu$ g with mean percent changes of -40.7% (2000  $\mu$ g; p<0.01) and -28.0% (2520  $\mu$ g; p<0.05) at Day 8, compared to an increase of 9.9% in placebo-treated individuals.
- The most common AEs occurring in  $\geq 5$  participants receiving GL0034 were decreased appetite, early satiety, nausea, dyspepsia, and vomiting.

#### ***Safety and Tolerability of Once-Weekly GL0034 (Utregrlutide) in Healthy Individuals. A Multiple-Ascending Dose Study. [Poster # 766-P, Sunday, June 25, 2023, 11:30am – 12:30pm PT, Hall B-C, Presented by Dr. Rajamannar Thennati]***

- Participants (n=36; BMI 18–28 kg/m<sup>2</sup>) were enrolled into 3 fixed-dose or increasing-dose cohorts and were randomized 3:1 to treatment with GL0034 or placebo. The cohorts demonstrated mean percent changes in body weight, ranging from -4.5% at the lowest dose (450 µg; p<0.001) at Day 29 to -10.7% at the highest increasing dose (450/900/1520 µg; p<0.001) at Day 52, compared with -0.5% and 2.2% in placebo-treated participants.
- ALT levels were observed within normal range at the start of the study and were reduced during treatment with all doses of GL0034 at Day 23 and Day 51. Additionally, reductions from baseline in levels of fasting insulin were noted in cohorts 2 and 3 with corresponding improvements in HOMA-IR.
- The most common AEs occurring in ≥5 participants receiving GL0034 included nausea, vomiting, and decreased appetite.

### **About GL0034**

GL0034 (utreglutide) is an investigational novel glucagon-like peptide 1 receptor agonist (GLP-1RA) in development as a once-weekly, long-acting, antidiabetic medication in patients with obesity and type 2 diabetes. Sun Pharma proceeded into its first-in-human Phase 1 clinical trial based on positive results of its pre-clinical trials in which GL0034 demonstrated robust antidiabetic effects in mice, including reductions in blood glucose levels as well as body weight. Further clinical studies are planned to confirm clinical safety and effectiveness, including a 12-week proof of concept study in obese adults with type 2 diabetes, with non-alcoholic fatty liver (NAFL) and non-alcoholic steatohepatitis (NASH) biomarkers.

### **About Sun Pharmaceutical Industries Ltd. (CIN - L24230GJ1993PLC019050)**

Sun Pharma is the world's fourth largest specialty generics company with presence in Specialty, 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, onco-dermatology and accounts for over 16% 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 Twitter @SunPharma\_Live.

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