## Sun Pharmaceutical Industries Limited

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## FOR IMMEDIATE RELEASE

# Sun Pharma Presents Data from Phase 1b/2a Study of GL0034 at the American Heart Association 2025 Scientific Sessions

Once Weekly Utreglutide (GL0034), a Glucagon-like
Peptide-1 Receptor Agonist showed Weight loss of 8% at week 14, Reduced Liver
Fat Content along with Blood Pressure in Post-menopausal Females
with Obesity

**MUMBAI, India and PRINCETON, N.J., November 12, 2025** – Sun Pharmaceutical Industries Ltd. (Reuters: SUN.BO, Bloomberg: SUNP IN, NSE: SUNPHARMA, BSE: 524715, "Sun Pharma" including its subsidiaries and/or associate companies) recently announced results from its Phase 1a/2b Study evaluating the tolerability, safety, pharmacokinetics and pharmacodynamics of GL0034, a novel long-acting GLP-1 receptor agonist, in post-menopausal females with obesity. The data were highlighted in poster presentation at the American Heart Association's (AHA) Scientific Sessions held from November 7-10, 2025, in New Orleans, USA.

The Phase 1b/2a study in Australia evaluated weekly subcutaneous utreglutide in post-menopausal women with obesity and MAFLD (Metabolic Dysfunction-associated Fatty Liver Disease). Participants experienced meaningful weight loss and waist circumference reduction, with a notable proportion achieving clinically significant outcomes compared to placebo.

Additional metabolic improvements included improved systolic blood pressure, reduced liver fat, and favorable changes in biomarkers linked to fibrosis and insulin sensitivity. The treatment also lowered serum uric acid levels, reinforcing its potential in addressing multiple aspects of metabolic dysfunction in this high-risk population.

Once weekly utreglutide dosing for 13 weeks was well tolerated in post-menopausal female participants with obesity and MAFLD. The most frequent AEs were gastrointestinal in nature-nausea, diarrhoea, and vomiting - which is consistent with the incretin class. One participant had a serious Treatment-Emergent Adverse Event, which was unrelated to the treatment.

"Obesity and metabolic liver diseases continue to place a growing burden on public health, especially among post-menopausal women who face unique challenges. The results from our early-stage study with utreglutide are encouraging and reflect our commitment to advancing therapies that can make a meaningful difference in patients' lives. We're pleased with the progress and remain focused on supporting better health outcomes." said Dilip Shanghvi, Chairman, Sun Pharma.

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"We observed encouraging reductions in liver fat and improvements across key metabolic parameters with utreglutide in post-menopausal women with obesity and MASLD." said Rohit Loomba, Professor of Medicine (with tenure), Chief, Division of Gastroenterology and Hepatology, University of California at San Diego. The treatment was well tolerated, with low discontinuation rate. These findings highlight utreglutide's potential in addressing MAFLD and related metabolic conditions. We look forward to seeing how this molecule progresses through future clinical development."

GL0034 was discovered and is being developed by Sun Pharma. Further clinical studies are planned to assess clinical safety and efficacy.

# **GL0034 Poster Presentation at the AHA 2025 Scientific Sessions**

A Phase 1b/2a Study of The Novel GLP-1 Receptor Agonist GL0034 (utreglutide) in the Treatment of MASLD. [Moderated Digital PosterMP444, Saturday, November 8, 2025, 01:11pm – 01:16pm CT, Population Science Zone, Moderated Digital Poster 11, Presented by Dr. Rajamannar Thennati]

- Participants (n=48; BMI ≥30 kg/m² Controlled attenuated parameter (CAP) ≥306 dB/m via FibroScan®; Liver fat content ≥10%, as assessed by MRI-PDFF) were randomized 3:1 to treatment with GL0034 (uptitration from 0.4 mg-1.6mg for 10 weeks and fixed dose of 2.4 mg for 3 weeks; total dose 17.6mg) or placebo for 13 weeks. The data from strata of post-menopausal females (52-69 years of age) is presented (17 in GL0034 treatment and 5 in placebo). At Week 14, the GL0034-treated females achieved a mean percent change in body weight of -8%, (P<0.001) and sustained beyond initial treatment exposure through Week 17, compared to -2.1% at Week 14 and -1.2% at Week 17 in placebotreated participants. Further, at week 14 and 17, 76% and 71% GL0034-treated female participants achieved a weight loss exceeding 10%. The mean BMI at baseline of GL0034-treated females was 43 kg/m², which improved to 39.7 and 39.8 kg/m² at weeks 14 and 17, respectively. Notably, 47% of female participants in class III and class II obesity group, showed one level lowering of obesity class.</p>
- The liver fat content was significantly decreased from baseline in participants treated with GL0034 with mean percent changes of -28.6% (*P*<0.01) compared to a change of -2.7% in placebo-treated individuals. The PRO-C3 levels significantly decreased from baseline (-12.6%, *P*<0.05) as compared to an increase of 11.8% in placebo-treated participants. About 35% of the females achieved >30% of relative liver fat content reduction as compared to none in placebo-treated group.
- The most common AEs occurring in ≥5 participants receiving GL0034 were decreased appetite, early satiety, nausea, dyspepsia, and vomiting.

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# **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. Further clinical studies are planned to assess clinical safety and effectiveness.

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

Sun Pharma is the world's leading specialty generics company with a presence in specialty, generics and consumer healthcare products. It is the largest pharmaceutical company in India and is a leading generic company in the U.S. as well as global emerging markets. Sun Pharma's high-growth global specialty portfolio spans innovative products in dermatology, ophthalmology, and onco-dermatology and accounts for about 20% 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 multicultural workforce drawn from over 50 nations. For further information, please visit www.sunpharma.com and follow us on LinkedIn & X (Formerly Twitter).

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