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## **Eli Lilly's Announcement Regarding Oral GLP-1 Orforglipron**

- **For the primary endpoint, orforglipron lowered HbA1c by 2.2% vs. 1.4% with oral semaglutide at the highest doses**
- **Participants taking the highest dose of orforglipron lost an average of 19.7 lbs (8.9 kg) (9.2%) vs. 11.0 lbs (5.0 kg) (5.3%) with oral semaglutide, a 73.6% relative improvement, in a key secondary endpoint**
- **The safety and tolerability of orforglipron were consistent with previous trials**

TOKYO, September 17, 2025 – [Chugai Pharmaceutical Co., Ltd.](#) (TOKYO: 4519) announced that [Eli Lilly and Company](#) (hereafter “Eli Lilly”, NYSE: LLY) issued a press release on September 17, 2025 (local time) regarding positive topline results from ACHIEVE-3, an open-label randomized Phase 3 clinical trial evaluating the safety and efficacy of orforglipron compared to oral semaglutide, administered according to approved label instructions, in 1,698 adults with type 2 diabetes inadequately controlled with metformin. The 52-week trial compared orforglipron (12 mg and 36 mg) to oral semaglutide (7 mg and 14 mg) across four active treatment arms to assess glycemic control and weight loss. At 52 weeks, orforglipron met the primary and all key secondary endpoints across each dose comparison vs. oral semaglutide, delivering greater improvements in HbA1c and weight.\*

In the ACHIEVE-3 trial, orforglipron met the primary endpoint and showed superiority vs. oral semaglutide, lowering A1C by an average of 1.9% (12 mg) and 2.2% (36 mg) compared to 1.1% (7 mg) and 1.4% (14 mg) with oral semaglutide at 52 weeks using the efficacy estimand.\*\* In a secondary endpoint, 37.1% of participants taking the highest dose of orforglipron achieved an A1C <5.7% compared to 12.5% taking the highest dose of oral semaglutide.<sup>1</sup> In key secondary endpoints, orforglipron was also superior to oral semaglutide for weight loss, and participants taking orforglipron lost an average of 14.6 lbs (6.6 kg) (6.7%; 12 mg) and 19.7 lbs (8.9 kg) (9.2%; 36 mg) compared to 7.9 lbs (3.6 kg) (3.7%; 7 mg) and 11.0 lbs (5.0 kg) (5.3%; 14 mg) with oral semaglutide, a 73.6% greater relative weight loss at the highest dose comparison. Orforglipron also showed clinically meaningful improvements across key cardiovascular risk factors, including non-HDL

cholesterol, systolic blood pressure and triglycerides.\*\*\*

The overall safety and tolerability profile of orforglipron in ACHIEVE-3 was consistent with previous trials. The most commonly reported adverse events were gastrointestinal-related and generally mild-to-moderate in severity. Treatment discontinuation rates due to adverse events were 8.7% (12 mg) and 9.7% (36 mg) for orforglipron vs. 4.5% (7 mg) and 4.9% (14 mg) for oral semaglutide. However, the study was not powered to compare the safety and tolerability of orforglipron and oral semaglutide. No hepatic safety signal was observed for orforglipron.

The detailed results of the ACHIEVE-3 trial will be presented at a future medical meeting and published in a peer-reviewed journal. Lilly expects to submit orforglipron for the treatment of type 2 diabetes to global regulatory agencies in 2026.

For the full text of Eli Lilly's press release, please refer to the Latest News via the following link:  
Lilly's oral GLP-1, orforglipron, superior to oral semaglutide in head-to-head trial  
<https://investor.lilly.com/>

This announcement is not expected to have an impact on Chugai's consolidated financial forecast for the fiscal year ending December 2025, which was announced on January 30, 2025.

\* Body weight for orforglipron 12 mg vs. oral semaglutide 14 mg was a prespecified secondary endpoint and showed nominal statistical significance using the efficacy estimand; however, it was not controlled for family-wise type 1 error for the efficacy estimand or treatment-regimen estimand.

\*\* The efficacy estimand represents efficacy had all randomized participants remained on study intervention (with possible dose interruptions and/or dose modifications) for 52 weeks without initiating additional antihyperglycemic medications (>14 days of use).

\*\*\* Not controlled for family-wise type 1 error.

#### Sources

1. American Diabetes Association. Standards of Care in Diabetes—2020 Abridged for Primary Care Providers. Clinical Diabetes 2020; 38(1):10–38.

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