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Eli Lilly's Announcement Regarding Oral GLP-1 Orforglipron (Statistically Significant Efficacy and a Safety Profile Consistent with Injectable GLP-1 Medicines in Phase III ACHIEVE-1 for Type 2 Diabetes)

TOKYO, April 18, 2025 -- Chugai Pharmaceutical Co., Ltd. (TOKYO: 4519) announced that Eli Lilly and Company (hereafter "Eli Lilly", NYSE: LLY) issued a press release on April 17, 2025 (local time) regarding the positive topline Phase 3 results from ACHIEVE-1, evaluating the safety and efficacy of orforglipron compared to placebo in adults with type 2 diabetes and inadequate glycemic control with diet and exercise alone.

In the first Phase 3 trial of the ACHIEVE program (n=559), orforglipron met the primary endpoint of superior A1C reduction compared to placebo at 40 weeks, lowering A1C by an average of 1.3% to 1.6% from a baseline of 8.0%, using the efficacy estimand.* In a key secondary endpoint, more than 65% of participants taking the highest dose of orforglipron achieved an A1C less than or equal to 6.5%, which is below the American Diabetes Association's (ADA) defined threshold for diabetes.[1] In an additional key secondary endpoint, participants taking orforglipron lost an average of 16.0 lbs (7.9%) at the highest dose.

The overall safety profile of orforglipron in ACHIEVE-1 was consistent with the established GLP-1 class. The most commonly reported adverse events were gastrointestinal-related (diarrhea, nausea, dyspepsia, constipation, vomiting) and generally mild to moderate in severity. Overall treatment discontinuation rates due to adverse events were 6% (3 mg), 4% (12 mg) and 8% (36 mg) for orforglipron vs. 1% with placebo. No hepatic safety signal was observed.

The ACHIEVE-1 results will be presented at ADA's 85th Scientific Sessions and published in a peer-reviewed journal. More results from the ACHIEVE Phase 3 clinical trial program will be shared later this year, along with findings from the ATTAIN Phase 3 clinical trial program evaluating orforglipron for weight management. Eli Lilly expects to submit orforglipron for weight management to global regulatory agencies by the end of this year, with the submission for the treatment of type 2 diabetes anticipated 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, demonstrated statistically significant efficacy results and a safety profile consistent with injectable GLP-1 medicines in successful Phase 3 trial https://investor.lilly.com/

This announcement is not expected to have an impact on Chugai's consolidated financial results for the fiscal year ending December 2025.

* The efficacy estimand represents efficacy had all participants remained on study intervention (with possible dose interruptions) for 40 weeks without initiating additional antihyperglycemic medications (>14 days of use).

Sources

1. American Diabetes Association. (n.d.). Understanding diabetes diagnosis. Diabetes Diagnosis & Tests | ADA. [Internet; cited April 2025]. Available from: https://diabetes.org/about-diabetes/diagnosis

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