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## New oral GLP-1 medicine for weight management and type 2 diabetes

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Once-daily tablet provides an alternative to other oral and injectable GLP-1 medicines

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EMA has recommended granting a marketing authorisation in the European Union for Foundayo (orforglipron), an oral GLP-1 receptor agonist for weight management and treatment of type 2 diabetes in adults.

For weight management, Foundayo is used alongside a healthy diet and physical activity in adults with obesity (see note 2) or overweight (see note 3) who have at least one weight-related health problem. For type 2 diabetes, Foundayo is used alongside a healthy diet and physical activity in adults with type 2 diabetes whose blood glucose levels are not sufficiently controlled. It can be used alone when metformin is not appropriate, or together with other diabetes medicines.

Obesity and overweight affect more than 2.5 billion people worldwide (see note 4) and increase the risk of serious health problems, including cardiovascular disease and type 2 diabetes. In 2021, excess body weight was associated with around 4 million deaths and 129 million disability-adjusted life years

worldwide (see note 5). Diabetes affects approximately 589 million adults (20 to 79 years) globally, with type 2 diabetes accounting for approximately 90% of all cases worldwide (see note 6). People with type 2 diabetes are at increased risk of complications such as heart attack, stroke, kidney disease, nerve damage and vision loss.

Foundayo can only be obtained with a prescription and will be available as a tablet taken once daily, providing an alternative to injectable and other oral GLP-1 receptor agonists. It can be taken at any time of day, with or without food. Treatment starts at a low dose, which is gradually increased according to the patient's response and how well they tolerate the medicine.

The active substance in Foundayo, orforglipron, is a small, non-peptide molecule that activates the receptor for glucagon-like peptide-1 (GLP-1). GLP-1 is a natural hormone involved in controlling appetite and blood glucose levels. As a non-peptide medicine, orforglipron is developed to be taken orally. By activating these receptors, orforglipron reduces appetite and increases feelings of fullness, helping people eat less and lose weight. It also lowers blood glucose by helping the pancreas release more insulin when blood glucose levels are high, reducing levels of glucagon (a hormone that raises blood glucose) and helping the body respond better to insulin.

EMA's recommendation for Foundayo in weight management is based on two studies involving 4,740 adults with obesity or overweight. One study included adults without type 2 diabetes but another weight-related health problem, while the other included adults with type 2 diabetes. After 72 weeks, participants treated with Foundayo lost around 5% to 11% of their body weight, depending on the dose of Foundayo they took, compared with around 2% to 2.5% in those who took placebo.

For type 2 diabetes, Foundayo was evaluated in four main studies involving 3,765 adults whose blood glucose was not adequately controlled with diet and physical activity alone or with other diabetes medicines. Depending on the study, Foundayo was used on its own or in combination with other diabetes medicines and was compared with placebo, dapagliflozin or oral semaglutide. The main measure of effectiveness was the change in HbA1c, a marker of blood

glucose control. Across the studies, Foundayo reduced HbA1c by around 1.2 to 1.9 percentage points, depending on the dose received. This compared with reductions in HbA1c of 0.4 to 0.8 percentage points with placebo, 0.8 percentage points with dapagliflozin 10 mg and 1.2 to 1.5 percentage points with oral semaglutide, at doses of 7 mg and 14 mg, respectively.

The most common side effects reported with Foundayo were nausea, vomiting and diarrhoea, which occurred more often while the dose was increased and became less frequent over time.

The opinion adopted by the CHMP is an intermediary step on Foundayo's path to patient access. The opinion will now be sent to the European Commission for the adoption of a decision on an EU-wide marketing authorisation. Once a marketing authorisation has been granted, decisions about price and reimbursement will take place at the level of each Member State, taking into account the potential role or use of this medicine in the context of the national health system of that country.

## Notes

1. The applicant for Foundayo is Eli Lilly Nederland B.V.
2. Obese is defined as having a body mass index (BMI) of at least 30 kg / m<sup>2</sup>.
3. Overweight is defined as having a BMI of least 27 kg / m<sup>2</sup> but below 30 kg / m<sup>2</sup>.
4. [Factsheet - World Health Organization: Obesity and overweight](#)
5. [Global Burden of Disease \(GBD\) 2021 Adult BMI Collaborators. Global, regional, and national prevalence of adult overweight and obesity, 1990–2021, with forecasts to 2050: a forecasting study for the Global Burden of Disease Study 2021 - The Lancet, 2025](#)
6. [International Diabetes Federation: Over 250 million people worldwide unaware they have diabetes, according to new IDF research - IDF Diabetes Atlas, 11th edition, 2025](#)

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