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NEWS IN BRIEF | 20 May 2022

Lilly's tirzepatide secures first approval in diabetes, paving path for dual-acting hormone mimetics

By Asher Mullard



The FDA's approval of [Lilly's tirzepatide](#) for type 2 diabetes is set to shake up the endocrinology space.

"This is the most effective drug yet approved for the treatment of type 2 diabetes," says Daniel Drucker, a clinician scientist and endocrinologist at the Lunenfeld-Tanenbaum Research Institute at Mount Sinai hospital. "I think it will be welcomed with enthusiasm."

Tirzepatide is the first peptide-based drug that mimics two gut hormones – glucagon-like peptide 1 (GLP1) and glucose-dependent insulintropic polypeptide (GIP) – to secure approval for the metabolic disorder. Synthetic versions of GLP1 first gained FDA approval in 2005, and these boost insulin levels and lower glucagon levels to regulate blood sugar and to suppress appetite. The GIP hormone also increases insulin but has context-dependent effects on glucagon. The overlapping effects of these hormones led Lilly to [design a dual agonist](#) peptide, based on the sequence of GIP.

Results from five pivotal type 2 diabetes trials – [SURPASS-1](#), [-2](#), [-3](#), [-4](#) and [-5](#) – validated this approach. The trials evaluated various doses of tirzepatide as monotherapy and in combination with other diabetes drugs, and compared the new drug to placebo, the GLP1 receptor agonist semaglutide and two long-acting insulins. Tirzepatide on average lowered blood sugar, as measured by HbA1c levels, by 1.7–2.4%, says Lilly. The drug outperformed its active comparators, lowering HbA1c by 0.5% more than semaglutide and by 0.9–1% more than long-acting insulins.

Tirzepatide also offers weight loss benefits, inducing average reductions of around 6.5–14% across dose levels. Semaglutide led to average weight loss of 7%, and placebo and insulin led to weight gain of 2%.

Side effects of the dual agonist included nausea and diarrhoea and decreased appetite, which are also associated with GLP1 receptor agonists. The drug also carries a boxed warning noting

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to weight gain of 2%.

Side effects of the dual agonist included nausea and diarrhoea and decreased appetite, which are also associated with GLP1 receptor agonists. The drug also carries a boxed warning noting a risk of thyroid C cell tumours in rats, but the relevance of this for humans has not been determined.

Tirzepatide will now compete in the crowded diabetes market, facing off against effective drugs with established safety profiles. Analysts forecast sales of over US\$6 billion for the drug by 2027, show data from the Cortellis database.

These sales are tied to hopes for the drug as an [anti-obesity contender](#). In April, [top-line results](#) from Lilly's SURMOUNT-1 trial of tirzepatide in nearly 2,400 patients who are obese or overweight but who do not have diabetes showed average weight reductions of 15–21% at 72 weeks, compared to 3% on placebo. Three more phase III weight-loss trials are due to readout in 2023.

Last year, the FDA approved high-dose [semaglutide for chronic weight management](#). In the largest placebo-controlled pivotal trial of this peptide in obese or overweight adults without diabetes, participants lost a placebo-adjusted [12.4%](#) of their body weight with 68 weeks of treatment.

Tirzepatide is also in development for non-alcoholic steatohepatitis (NASH), an inflammatory disease of the liver.

[A pipeline](#) of multi-targeted hormone mimetics are in trials for metabolic diseases. Amgen's phase I candidate AMG 133 consists of a GLP1-like peptide conjugated to an antibody targeting the GIP receptor. GLP1 and glucagon receptor co-agonists in phase II development include AstraZeneca's cotadutide and Boehringer Ingelheim's BI 456906. Lilly's phase II tri-agonist LY3437943 emulates GLP1, GIP and glucagon.

But co-agonist peptides have disappointed in the clinic in the past, including dual GLP1 and GIP candidates, cautions Drucker. "I don't think it's a matter of making a co-agonist or triple agonist and automatically being guaranteed a path to success." Molecular design, dosing, and more all come into play. "It's not as predictable as we would like. It's still a combination of excellent science and a little bit of luck."

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