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MEDIA RELEASE

US FDA accepts Sandoz applications for proposed in-house development of generic tirzepatide GLP-1s

- Sandoz received US FDA file acceptances for generic tirzepatide autoinjector applications
- Proposed generic tirzepatide was developed in-house by Sandoz
- Applications address same indications covered by reference medicines, including type-2 diabetes and weight management

Basel, 29 June 2026 – Sandoz (SIX:SDZ/OTCQX:SDZNY), the global leader in affordable medicines, today announces that the US Food and Drug Administration (FDA) has accepted for review two Abbreviated New Drug Applications (ANDAs) for generic versions of tirzepatide. The ANDAs seek approval for an in-house Sandoz generic version of the tirzepatide autoinjector, a generic gastric inhibitory polypeptide receptor and glucagon-like peptide-1 (GLP-1) receptor agonist.

Both applications, which were filed under the FDA's generic pathway, address all indications of the reference medicines, Mounjaro®+ and Zepbound® ++. For Mounjaro® +, this would be as an adjunct to diet and exercise to improve glycemic control in adults and paediatric patients 10 years of age and older with type 2 diabetes mellitus. For Zepbound®++, this would be in combination with a reduced-calorie diet and increased physical activity, to reduce excess body weight and maintain weight reduction long term in obese or overweight adults in the presence of at least one weight-related comorbid condition and to treat moderate to severe obstructive sleep apnea (OSA) in adults with obesity[1] for weight management.[1,2]

Claire D'Abreu-Hayling, President, Generics Development and Chief Scientific Officer says: "Sandoz is building its GLP-1 development platform and this submission reflects true in-house innovation. It represents a key first step in our efforts to bring this medicine to market and underscores our ambition to increase competition and expand affordability in a critical area of healthcare need. With type-2 diabetes remaining the costliest chronic condition in the US and obesity rates having tripled since 1960, access to effective treatment options is more important than ever."[3]

Subject to FDA approval, Sandoz tirzepatide could be one of the first generic tirzepatide products available for patients in the US on market formation. Generic tirzepatide was developed in-house at Sandoz, combining the Company's expertise in small molecule and device development with its biosimilar expertise for advanced techniques.

The GLP-1 treatment area represents a long-term market opportunity, complementing the broader growth outlook for biosimilar and generic medicines. Reference medicines with a combined value of more than USD 650 billion are expected to lose patent protection over the next decade.[4]

Sandoz is developing a competitive GLP-1 pipeline across key global markets, addressing each opportunity with a mix of internal capabilities and strategic external partnerships across development and manufacturing. This approach maximises value and optimises capital deployment across the business.

Sandoz is committed to helping millions of patients access critical and potentially life-changing medicines sustainably and affordably, with a leading global portfolio comprising 1,300 quality generics and a further 400 generic assets in various stages of development.

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[+] Mounjaro® is a registered trademark of Eli Lilly and Company.
[++] Zepbound® is a registered trademark of Eli Lilly and Company.

DISCLAIMER

This Media Release contains forward-looking statements, which offer no guarantee with regard to future performance. These statements are made on the basis of management's views and assumptions regarding future events and business performance at the time the statements are made. They are subject to risks and uncertainties including, but not confined to, future global economic conditions, exchange rates, legal provisions, market conditions, activities by competitors and other factors outside of the control of Sandoz. Should one or more of these risks or uncertainties materialise or should underlying assumptions prove incorrect, actual outcomes may vary materially from those forecasted or expected. Each forward-looking statement speaks only as of the date of the particular statement, and Sandoz undertakes no obligation to publicly revise any forward-looking statements, except as required by law.

REFERENCES

[1] Mounjaro. Prescribing Information. Available at: https://pi.lilly.com/us/mounjaro-uspi.pdf
[2] Zepbound. Prescribing Information. Available at: https://pi.lilly.com/us/zepbound-uspi.pdf
[3] Pearson, S. D., Whaley, C. M., & Emond, S. K. (2025). Affordable access to GLP-1 obesity medications: strategies to guide market action and policy solutions in the US. Journal of comparative effectiveness research, 14(9), e250083. https://doi.org/10.57264/cer-2025-0083
[4] Covers US and EU markets (2026–2035). Originator sales and LoE based on internal analysis of data from multiple subscription databases. Generics data accessed in June 2025; biosimilar data accessed in September 2025.

ABOUT SANDOZ

Sandoz (SIX: SDZ; OTCQX: SDZNY) is the global leader in affordable medicines, with a growth strategy driven by its Purpose: pioneering access for patients. More than 20,000 colleagues of 100 nationalities work together to ensure over one billion patients are reached by Sandoz, generating substantial global healthcare savings and an even larger social impact. Its leading portfolio of approximately 1,300 medicines addresses diseases from the common cold to cancer. Headquartered in Basel, Switzerland, Sandoz traces its heritage back to 1886. In 2026, Sandoz celebrates 20 years of pioneering biosimilars, 80 years of antibiotics manufacturing and 140 years of heritage. In 2025, Sandoz recorded net sales of USD 11.1 billion.

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