



Tandem t:slim X2 Insulin Pump Now Compatible with Lyumjev Ultra-rapid Acting Insulin in European Union

September 19, 2024

SAN DIEGO--(BUSINESS WIRE)--Sep. 19, 2024-- Tandem Diabetes Care, Inc. (NASDAQ: TNDM), a leading insulin delivery and diabetes technology company, today announced that its t:slim X2 insulin pump with Control-IQ automated insulin delivery (AID) technology is now cleared for use with Eli Lilly and Company's Lyumjev® (insulin lispro-aabc injection) ultra-rapid acting insulin in the European Union (EU).

"High satisfaction and quality of life benefits were recently shown in a clinical study using Lyumjev with Control-IQ technology,"¹ said Jordan Pinsker, MD, Chief Medical Officer at Tandem Diabetes Care. "Ultra-rapid acting insulin is a popular choice for people living with diabetes due to its fast response time. We are proud to be able to offer Lyumjev compatibility with our t:slim X2 pump as part of an AID system in the EU, providing more flexibility for our customers in these countries."

Lyumjev was authorized for general use in insulin pumps in the EU in 2020, but pump manufacturers are required to perform extensive testing to verify compatibility with individual insulin pumps and AID systems. Tandem and Lilly collaborated to support the clinical trial showing benefits of using Lyumjev with Control-IQ technology. The companies continue to work to secure Lyumjev compatibility for the t:slim X2 pump in other regions and to secure Lyumjev compatibility for the Tandem Mobi pump.

Please see Lyumjev Full Prescribing Information including Patient Prescribing Information. For additional questions, please access [Lyumjev \(previously Liumjev\) | European Medicines Agency \(EMA\) \(europa.eu\)](#).

The t:slim X2 pump is currently cleared for use with Humalog and Novolog/NovoRapid U-100 insulins globally, and Admelog/Insulin lispro Sanofi and Trurapi/Insulin aspart Sanofi U-100 insulins in Canada and selected EU countries.

1. Levy CJ, Bailey R, Laffel LM, et al. Multicenter Evaluation of Ultra-Rapid Lispro Insulin with Control-IQ Technology in Adults, Adolescents, and Children with Type 1 Diabetes. *Diabetes Technol Ther.* 2024 Sep;26(9):652-660.

About Tandem Diabetes Care

Tandem Diabetes Care, a global insulin delivery and diabetes technology company, manufactures and sells advanced automated insulin delivery systems that reduce the burden of diabetes management, while creating new possibilities for patients, their loved ones, and healthcare providers. The Company's pump portfolio features the Tandem Mobi system and the t:slim X2 insulin pump, both of which feature Control-IQ advanced hybrid closed-loop technology. Tandem Diabetes Care is based in San Diego, California. For more information, visit tandemdiabetes.com.

Follow Tandem Diabetes Care on X @tandemdiabetes; use #t:slimX2 #TandemMobi and #TandemDiabetes.

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Forward Looking Statement

This press release contains "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, that concern matters that involve risks and uncertainties that could cause actual results to differ materially from those anticipated or projected in the forward-looking statements. These forward-looking statements relate to, among other things, Tandem's ability to expand compatibility of its technology with Lyumjev. These statements are subject to numerous risks and uncertainties, including Tandem's ability to secure Lyumjev compatibility for the t:slim X2 pump in other regions and/or the timing thereof, the ability to secure Lyumjev compatibility for the Tandem Mobi pump in any region and/or the timing thereof, as well as other risks and uncertainties identified in the Company's most recent Annual report on Form 10-K and its other filings with the Securities and Exchange Commissions. Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this release. The Company undertakes no obligation to update or review any forward-looking statement in this press release because of new information, future events or other factors.

Important Safety Information

RX ONLY. Indications for Use: The t:slim X2 insulin pump is intended for the subcutaneous delivery of insulin, at set and variable rates, for the management of diabetes mellitus in persons requiring insulin. The pump is able to reliably and securely communicate with compatible, digitally connected devices. Control-IQ technology is intended for use with a compatible continuous glucose monitor (CGM) and the t:slim X2 insulin pump to automatically increase, decrease, and suspend delivery of basal insulin based on CGM readings and predicted glucose values. It can also deliver correction boluses when the glucose value is predicted to exceed a predefined threshold. The pump is indicated for use in persons six years of age and greater who require a total daily insulin dose of at least 10 units and who weigh at least 25 kilograms. The pump is intended for single patient use.

Refer to the User Guide for a list of compatible insulins.

WARNING: Control-IQ technology should not be used by anyone under the age of 6 years old. It should also not be used in users who require less than 10 units of insulin per day or who weigh less than 25 kilograms.

The System is not indicated for use in pregnant women, people on dialysis, or critically ill users. Do not use the System if using hydroxyurea.

Users of the pump and the System must: be willing and able to use the insulin pump, CGM, and all other system components in accordance with their respective instructions for use; test blood glucose levels as recommended by their healthcare provider; demonstrate adequate carb-counting skills; maintain sufficient diabetes self-care skills; see healthcare provider(s) regularly; and have adequate vision and/or hearing to recognize all functions of the pump, including alerts, alarms, and reminders. The t:slim X2 pump must be removed before MRI, CT, or diathermy treatment. Visit tandemdiabetes.com/safetyinfo for additional important safety information.

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