

Transdermal Specialties Global (TSG) Completes a Phase 3 Clinical Trial of the Trans- Insulin™ Transdermal Patch

TSG's U-Strip™ Has Successfully Achieved in Type-2 Diabetics the FDA Standard of 70% of the time, maintaining the Glucose Range Between 70 and 180 mg/dl,

CLAYMONT, DE, UNITED STATES, June 24, 2022 /EINPresswire.com/ -- Transdermal Specialties Global, a pioneer in ultrasonic active patch delivery systems (www.u-strip.com), has successfully completed a phase 3 clinical trial of a patented transdermal patch using [the U-Strip™](#) transdermal insulin delivery system. TSG conducted a 14-day trial to test the U-Strip™ ability to regulate the glucose level in Type-2 Diabetics and meet the Time in Range requirements set by the FDA.



Trans-Insulin™ Transdermal Patch

The U-Strip™ is a patented [transdermal insulin delivery patch system](#) that uses special ultrasound frequencies to expand the pores of the skin and deliver insulin into the bloodstream – No Needles. Insulin is too large to be absorbed by the skin normally. The use of ultrasound dilates the skin pores and pushes the drug into the tissue. Now entering Phase-3 clinical trials in both the United States and South Korea, the U-Strip™ Insulin system is nearing regulatory acceptance.

The Time in Range approach reduced the time for the Phase-3 clinical trial of a Transdermal Insulin patch from 90 days to meet A1C equivalency after just a 14-day study.

The results show the trial successfully met both safety and glycemic endpoints and demonstrated no occurrences of severe adverse events, no severe hypoglycemia and diabetic ketoacidosis and no Somogyi Effect.

The overall Time in Range (defined as 70-180 mg/dL) was an average of 95%, well over the FDA standard of 70%.

The study met primary endpoints (increasing overall Time in Range), as well as secondary endpoints (decreasing overall time above and below range). Patients also reported being extremely satisfied with their experience overall, with 96% agreeing that the system was easy to use and 87% agreeing that the system improved their quality of life.

The trial, conducted over 14 days with 6 Type-2 diabetic males, was performed using a combination device containing a special transdermal insulin patch loaded with 75 units of Lispro insulin, a Transducer Coupler and a control device programmed to reduce the starting glucose of the patient to the range of a Healthy Normal non-Diabetic (range of 85 to 110 mg./dl). The control algorithm then stabilizes the glucose level of the patient between 85 and 110 mg/dl. The glucose dropped by 40 points in both subjects in the first 10 minutes and automatically switched to the stabilization setting delivering micro-doses of insulin every minute to maintain the glucose between 85 and 110. The Slower dose setting, delivers 3.41 units of insulin per hour working like the pancreas, placing minute doses to prevent a rise.

This provided superior Time in Range controls for all subjects. The Bolus button delivers 4 units of insulin in 15 minutes to counteract a glucose spike from the meal. The test proved the subject could press the bolus button during the meal preventing the spike and returning the glucose back to stabilization automatically. The system is designed to simplify diabetes management providing an extra layer of protection for the times one may miscalculate their carbohydrates or forget a pre-meal bolus.

The study findings at various levels of glucose control, are promising and demonstrate that the [Trans-Insulin™](#) Transdermal Patch using the patented U-Strip™ ultrasonic delivery patch system has tremendous potential for meaningfully reducing burden and enhancing quality of life.

TSG located in Frederick, MD is committed to developing innovative drug delivery systems that enhance health and improve the quality of life. The company has developed an Ultrasonic active patch delivery system U-STRIP™ that uses special ultrasound frequencies to expand the pores of the skin and deliver drugs into the bloodstream...TSG's first product is a painless Needle-Free transdermal insulin delivery patch system. Since 2016, TSG has been a pioneer in the development of ultrasonic technologies for the pharmaceutical and cosmetic industry.

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