

# The PROMISE Study: An Evaluation of the Safety and Accuracy of the Next Generation 180-Day Long-term Implantable Eversense CGM System

Satish K. Garg<sup>1</sup>, David Liljenquist<sup>2</sup>, Bruce Bode<sup>3</sup>, Mark P. Christiansen<sup>4</sup>, Timothy S. Bailey<sup>5</sup>, Ronald L. Brazg<sup>6</sup>, Douglas Denham<sup>7</sup>, Anna R. Chang<sup>8</sup>, Halis K. Akturk<sup>1</sup>, Andrew Dehennis<sup>9</sup>, Katherine S. Tweden<sup>9</sup>, Francine R. Kaufman<sup>9</sup>

1. **University of Colorado, Aurora, CO, USA**; 2. Rocky Mountain Diabetes Center, Idaho Falls, USA; 3. Atlanta Diabetes Associates, Atlanta, GA, USA; 4. Diablo Clinical Research, Walnut Creek, CA, USA; 5. AMCR Institute, Escondido, CA, USA; 6. Rainier Clinical Research Center, Renton, WA, USA; 7. Clinical Trials of Texas Inc, San Antonio, TX, USA; 8. John Muir Health, Concord, CA, USA; 9. Senseonics, Germantown, MD, USA

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# Disclosure Information

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# Background

- The Eversense CGM system is the only long-term implantable CGM system approved for use
- Pivotal studies have shown a MARD of
  - **8.5% for the 90-day US product**
  - **9.4% for the 180-day European system**
- Key Eversense CGM system attributes include:
  - Fluorescent-based optical methodology
  - Transmitter placed on the skin over the sensor allows for
    - **On-body vibratory alerts**
    - Mild silicone-based adhesive with low rates of skin irritation
  - Inserted and removed by certified health care providers in a short in-office procedure
  - **No interference with Paracetamol or Vitamin C**



# Purpose

- The prospective, multi-center **PROMISE Study** evaluated the safety and accuracy of the next-generation Eversense CGM System for up to 180 days
  - A **subset of subjects had a second sensor (Sacrificial Boronic Acid {SBA} sensor)** inserted with a specific modification to reduce oxidation of the glucose-binding indicator chemistry

# Materials and Methods

- **10 clinic visits**, between day 1-180, lasting up to 10 hours, comparing CGM and reference glucose from YSI 2300 glucose analyzer (YSI)
- Hyperglycemia and hypoglycemia challenges to assess glucose between 40-400mg/dL
- **96 of the 181 subjects had 2 sensors, one in each arm**
  - **43 subjects had a modified second sensor (SBA sensor) and 53 had a second sensor identical to the primary sensor**
- **The CGM prompts 2 calibrations/day to day 21, after it can prompt 1 calibration/day**

# Baseline Patient Characteristics

Demographic	Value
Gender n (%)	
Male	85 (47.0)
Female	96 (53.0)
Age (years)*	48.6 (14.9)
Ethnicity n (%)	
Hispanic	23 (12.7)
Non-Hispanic	158 (87.3)
Race n(%)	
<b>Caucasian</b>	<b>163 (90.1)</b>
<b>Black or African American</b>	<b>10 (5.5)</b>
<b>Asian</b>	<b>4 (2.2)</b>
<b>American Indian or Alaska Native</b>	<b>2 (1.1)</b>
<b>Native Hawaiian or Other Pacific Islander</b>	<b>0 (0.0)</b>
<b>More than One Race Self-Identified</b>	<b>2 (1.1)</b>
Years since diabetes diagnosis (years)*	<b>22.0 (13.3)</b>
Diabetes type n (%)	
<b>Type 1</b>	<b>126 (69.6)</b>
<b>Type 2</b>	<b>55 (30.4)</b>
HbA1c (%)*	7.6 (1.3)

# Accuracy by Glucose Range: Primary Sensor

YSI Glucose Range (mg/dL)	Number of Paired CGM and YSI Reference Points	Mean Percent 20/20% of Reference	Mean Absolute Relative Difference, MARD (%)	Median Absolute Relative Difference (%)
<b>Overall</b>	<b>49613</b>	<b>92.9</b>	<b>9.1</b>	<b>6.7</b>
40 – 60	2281	89.4	9.4	7.0
61 – 80	5270	92.2	8.8	7.0
81 – 180	19001	90.9	9.0	6.7
181 – 300	14578	94.7	7.7	5.9
301 – 350	6862	96.5	7.1	5.9
351 – 400	1510	93.9	8.0	6.3

# Accuracy by Day: Primary Sensor

Day Number	Number of Paired CGM and YSI Reference Points	Mean Percent 20/20% of Reference	Mean Absolute Relative Difference, MARD (%)	Median Absolute Relative Difference (%)
Day 1	5584	89.0	<b>11.0</b>	<b>8.0</b>
Day 7	2724	91.3	9.6	7.2
Day 14	2318	91.7	9.2	6.8
Day 22	6198	93.6	9.1	6.9
Day 30	6488	94.8	8.4	6.1
Day 60	6345	95.8	7.7	6.0
Day 90	6039	94.4	8.2	6.2
Day 120	5173	93.3	<b>9.2</b>	<b>6.7</b>
Day 150	4227	92.7	<b>9.6</b>	<b>6.9</b>
Day 180	4517	89.6	<b>10.4</b>	<b>7.5</b>

# Comparison between Primary and SBA Sensors

	Primary Sensors # of Paired Points – 49,613	SBA Sensors # of Paired Points – 12,034
% with 20/20%	92.9%	93.9%
<b>MARD</b>	<b>9.1%</b>	<b>8.5%</b>
Confirmed alert detection rate 70 mg/dL	93%	94%
Confirmed alert detection rate 180 mg/dL	99%	99%
<b>MAD between 40-60 mg/dL</b>	<b>9.4%</b>	<b>7.5%</b>
<b>MAD between 61-80 mg/dL</b>	<b>8.8%</b>	<b>7.7%</b>
<b>Survival to 180 days</b>	<b>65%</b> <b>98% day 90, 90% day 120,</b> <b>74% day 150</b>	<b>90%</b> <b>96% day 90 and day 120</b> <b>94% day 150</b>



# Safety

- The HbA1c was 7.6% at baseline, 7.2% at 90 days, 7.3% at day 180
- No SAEs related to device or insertion/removal procedures
- No unanticipated AEs or UADEs
- 279 sensors (85 single sensors + 96 dual sensors + 2 replacements), resulting in 558 insertion/removal procedures
  - **2 mild skin infections**
  - Incision infection rate in 1.1% of subjects or 0.36% of the total insertion and removal procedures

# Summary

- The effectiveness measurements for the primary sensors:
  - **92.9% of the CGM readings were within 20/20% of YSI values**
  - **9.1% MARD-Overall**
  - **8.8 - 9.4% MAD for hypoglycemia range**
- The effectiveness measurements for the subset of **SBA sensors**:
  - 93.9% of CGM readings were within 20/20% of YSI values
  - **8.5% MARD**
  - **<8% MAD for hypoglycemic range**
- The addition of SBA to sensor chemistry appears to result in sensors with slower indicator degradation kinetics increasing sensor longevity and improving sensor accuracy

# Conclusion

- As shown by the PROMISE study, the next-generation Eversense CGM system:
  - **Safe and accurate for up to 180 days**
  - **Allows for a single calibration/day** on most days of system wear
  - Should be considered a welcomed addition to options available for real-time CGM