

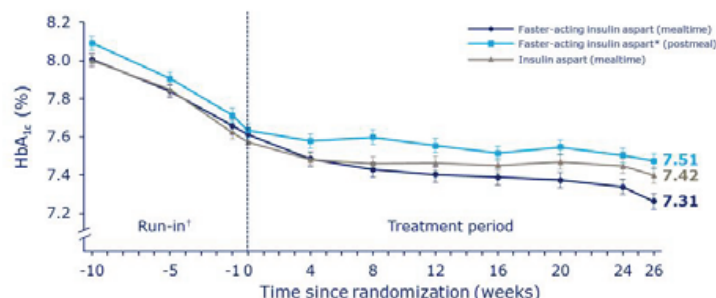
## Presentation 293-OR / 293 Double-Blind Mealtime Faster-Acting Insulin Aspart vs. Insulin Aspart in Basal-Bolus Improves Glycemic Control in T1D: The Onset® 1 Trial

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### Abstract:

Limiting excursions of postprandial glucose (PPG) is desirable in people with diabetes. This multicenter, treat-to-target, phase 3 trial evaluated the efficacy of faster-acting insulin aspart (faster aspart) in T1D. Primary endpoint was change from baseline in HbA<sub>1c</sub> after 26 weeks treatment. Post run-in, adult subjects were randomized to double-blind mealtime faster aspart (n=381), or insulin aspart (IAsp; n=380), or open-label postmeal faster aspart (n=382); each with insulin detemir. HbA<sub>1c</sub> was reduced for faster aspart and IAsp (Figure), confirming non-inferiority to IAsp for both mealtime and postmeal dosing (est. treatment diff. [ETD], % [95% CI]: mealtime, -0.15 [-0.23; -0.07]); postmeal, 0.04 [-0.04; 0.12]); HbA<sub>1c</sub> reduction was significantly greater for mealtime faster aspart vs. IAsp. Superiority to IAsp for 2 h PPG increment during a standardized meal test was confirmed for faster aspart (ETD: -0.67 [-1.29; -0.04] mmol/L; -12.01 [-23.33; -0.70] mg/dL). 1 h PPG increment was also reduced (ETD: -1.18 [-1.65; -0.71] mmol/L; -21.21 [-29.65; -12.77] mg/dL). No significant differences in overall rate of severe or confirmed hypoglycemic episodes (plasma glucose <3.1 mmol/L [56 mg/dL]). In summary, faster aspart effectively improved glycemic control with superior PPG control for mealtime faster aspart vs. IAsp, representing a clinical advance in treating T1D.

Figure: Mean HbA<sub>1c</sub> (%) over time.



\*Faster-acting insulin aspart dosed 20 min after a meal. †After initial screening, an 8-week run-in period was allowed for the optimization of basal insulin detemir. Full analysis set; observed data. Error bars: ± standard error (mean).