MK-1293, a biosimilar insulin glargine under development, was tested in a phase 3, randomized, active-controlled, open-label 24-week trial using Lantus™ as the originator benchmark among patients with type 2 diabetes. MK-1293 uses the same amino acid sequence as Lantus, noted investigator Michael Crutchlow, MD, Merck clinical director in late-stage diabetes research, at his American Diabetes Association 2016 poster presentation, as well as the same production cell type (E. coli) and the same pharmaceutical formulation. The trial enrolled 531 people with type 2 diabetes (HbA1c ≤11.0%) eligible for or taking basal insulin (≥10 U/day). While continuing on oral agents and prandial insulin, participants were randomized 1:1 to once daily MK-1293 (n=265) or Lantus (n=266) guided by a fasting glucose-based dosing algorithm with a fasting fingerstick glucose target of >70 and ≤100 mg/dL. The primary efficacy objective was non-inferiority of change from baseline HbA1c (margin of 0.40%) MK-1293 vs. Lantus at week 24.

A pre-specified stratification separated patients based on whether or not they were taking insulin at screening. Mean age at baseline was ~57 years (~55% male), and mean HbA1c was 8.3±1.3 for MK-1293 and 8.4±1.2 for Lantus.

The primary efficacy endpoint of HbA1c change from baseline (%), Dr. Crutchlow said, was -1.28 (-1.41, -1.15) for MK-1293 and -1.30 (-1.43, -1.18) for Lantus. The change of 0.03% (-0.12, 0.18) fell within non-inferiority boundaries. The changes, expectedly, were greater among patients who at baseline were insulin-naïve (-1.8 [-2.14, -1.48] for MK-1293 and -0.96 [-1.20, -0.72]) for Lantus. For those already taking insulin they were -0.96 (-1.20, -0.72) for MK-1293 and -0.92 (-1.07, -0.76) for Lantus.
Effects on the proportion of patients achieving HbA$_{1c}$ goals (<7.0% and <6.5%), fasting plasma glucose goals, and 7-point self-monitored plasma glucose goals, were also similar.

Immunological adverse events were uncommon and similar between treatment groups. Only 1 systemic allergic reaction was reported in a patient receiving MK-1293 (1/263, 0.4%). Anti-insulin antibodies (AIA) among patients who were AIA negative at baseline, were observed in 19.3% of patients receiving MK-1293 and in 14.9% of those receiving Lantus. There was no clear relationship between AIA positivity, AIA titer, or N-AIA positivity with HbA$_{1c}$ or insulin dose.

Dr. Crutchlow commented in an interview that the availability of effective biosimilar insulin would likely reduce prices. “This will make insulin more attainable and diabetes easier to manage for some people,” he said.

“Overall, this study demonstrated similar efficacy and safety between MK-1293 and Lantus in type 2 diabetes mellitus subjects over 24 weeks,” Dr. Crutchlow concluded.