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Redefining Convenience: Clinical Outcomes of Once-Weekly Basal Insulins

## Announcer:

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## Dr. Tsimikas:

This is CME on PACE CME and ReachMD, and I'm Dr. Athena Philis-Tsimikas. And today, I will be speaking to you on the efficacy and safety of new once-weekly insulins.

We're going to jump right into it, there are two current once-weekly insulins, which are now in testing phases and have completed their series of phase 3 clinical studies. And some countries, have available already insulin icodec. So, I'm going to first discuss insulin icodec and the series of trials conducted there, looking at efficacy and safety.

For the insulin icodec trials, there were 6 trials as part of the ONWARDS series, ONWARDS-1 through 6. There were three studies that were done in insulin naive type 2 diabetes, and that was ONWARDS-1, 3 and 5. In ONWARDS-5, there was an additional use of a titration app that assisted the patient in dosing, and this was done in a real-world environment.ONWARDS-3 was a blinded study, so it really allowed us to look at what the differences might be between using a once-daily basal insulin and a once-weekly insulin.

ONWARDS-2 and 4 were studies that were conducted in insulin-experienced type 2 diabetes, so people that had been on either basal insulin alone or basal bolus and looking at what converting over from a once-daily to a once-weekly might show. Was it feasible and resulting inefficacious glucose management? And then, ONWARDS-6 was conducted in patients with type 1 diabetes.

So, what were the results of these series of 6 studies? And if we looked first at the insulin-naive studies, patients in all of those studies achieved hemoglobin A1C that was superior to the once-daily insulin. Their baseline starting hemoglobin A1Cs ranged between 8.5 to 8.9%. The A1Cs dropped on average between 1.3 to 1.6% with the greater drop in the insulin icodec once-weekly group compared to the once-daily group.

Looking at hypoglycemia from a safety perspective, in all these trials there was a very low rate of hypoglycemia with less than one event per participant per year occurring in all those trials.

So, really, very safe as well as very efficacious in lowering glucose in these series of trials in those starting out insulin.

Turning to the studies in which patients were already taking insulin and switched, what we saw, their baseline A1Cs were between 8.1% in the ONWARDS-2 and 8.3% in ONWARDS-4. In this case, the A1C drop in ONWARDS-2 was once again superior to basal once-daily insulin, degludec, which was used. And again, very low rates of hypoglycemia. Less than one event per participant per year. In the ONWARDS-4, which was the group that was on basal bolus insulin, so this was a group that was a little bit more advanced in terms of their insulin need. Their diabetes had been longer. And in that situation, the glucose lowering was equivalent between both glargine U-100 as the once-weekly icodec. There was a slightly higher rate, overall rate, of hypoglycemia in both these groups, but no difference between the groups.

So, overall, excellent results both for glucose lowering as well as safety.

The next series of trials, which were conducted in type 2 diabetes, were using once-weekly efsitora alpha. And these were designed in a very similar way.

If we look at first the basal initiation studies, the baseline hemoglobin A1C was about 8.2, 8.3% in these studies. They were year-long studies, and the drop in A1C was about 1.3% in both of these studies. They were equivalent drop whether you were using basal oncedaily versus basal once-weekly. And looking at hypoglycemia events, very low events in all of the arms, again, similar to the ONWARDS less than one event per patient year.

People that were already on basal insulin, switching to once-daily or once-weekly basal insulin. That was the QWINT-3 trial. People came in with baseline A1C of 7.8% and their A1C dropped 0.75 or 0.86% in those studies at 26 weeks. And again, very low rates of hypoglycemia.

If you look at the QWINT-4, which was again, our more advanced patients with type 2 diabetes on basal bolus insulin already, mean A1C was 8.2% and they had a drop of 1.07 in either glargine U-100 arm or the once-weekly efsitora. With, again, slightly higher hypoglycemia rates in both the arms.

So, once again, demonstrating glucose glycemic efficacy as well as safety.

So, what does this really mean for us as practitioners that want to provide insulin to our patients? We can now, I think, safely and efficaciously, provide a basal insulin once-weekly. Our participants were extremely happy with these outcomes and are looking forward to being able to use these insulins in the future.

Thanks so much for your time.

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