Background and aims

Two scientific questions were addressed by two estimands (Figure 2).

Methods

- **Patients**: 790 patients (72% male, 75% non-Hispanic white, 23% Hispanic, 2% other) with type 2 diabetes, mean age 58 years, duration of diabetes 19.6 years for patients in South Korea. †Metformin, a sodium glucose cotransporter 2 inhibitor, a daily dose of 1,200 mg, was used as a background treatment.

- **Randomization**: Patients were randomized to receive once-daily oral semaglutide with flexible sulfonylurea, and/or a thiazolidinedione. OAD, oral antidiabetes drug.

- **Primary endpoints**: Change from baseline to week 52 in HbA1c, achieved HbA1c ≤7.0% at week 52, and changes in body weight.

- **Secondary endpoints**: Number of treatment-emergent adverse events, hypoglycemia (any grade), and severe hypoglycemia.

- **Safety**: Rescue medication was administered in 15.9% of patients receiving sitagliptin, and 8.3% were receiving oral semaglutide 7 mg, and 9.0% were receiving oral semaglutide 3 mg (dose extension phase (currently ongoing).

- **Conclusions**: Oral semaglutide flexible dose adjustment was superior to sitagliptin in reducing HbA1c and body weight. Rescue medication was initiated in 15.9% of patients receiving sitagliptin, and 8.3% were receiving oral semaglutide 7 mg, and 9.0% were receiving oral semaglutide 3 mg (dose extension phase (currently ongoing).

Results

- **Primary endpoint**: The primary endpoint was the achievement of HbA1c ≤7.0% at week 52 (Figure 4).

- **Secondary endpoint**: Oral semaglutide flexible dose adjustment was superior to sitagliptin and had a similar effect on body weight reduction (Figure 6).

Discussion

- **Effect on body weight**: Oral semaglutide flexible dose adjustment significantly reduced HbA1c and body weight.

- **Importance**:

  - Advantages (ADA): were more common with oral semaglutide, most of which were transient and did not result in discontinuation due to lack of efficacy.
  - Limitation: event adjudication committee-confirmed neoplasms occurred in 3.2% of patients.

Conclusion

- **Conclusion**: Oral semaglutide was well tolerated, with a safety profile consistent with the GLP-1 class.