



Saxagliptin Assessment of Vascular Outcomes Recorded in Patients with Diabetes Mellitus (SAVOR) – TIMI 53

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On behalf of the SAVOR-TIMI 53
Steering Committee and Investigators**

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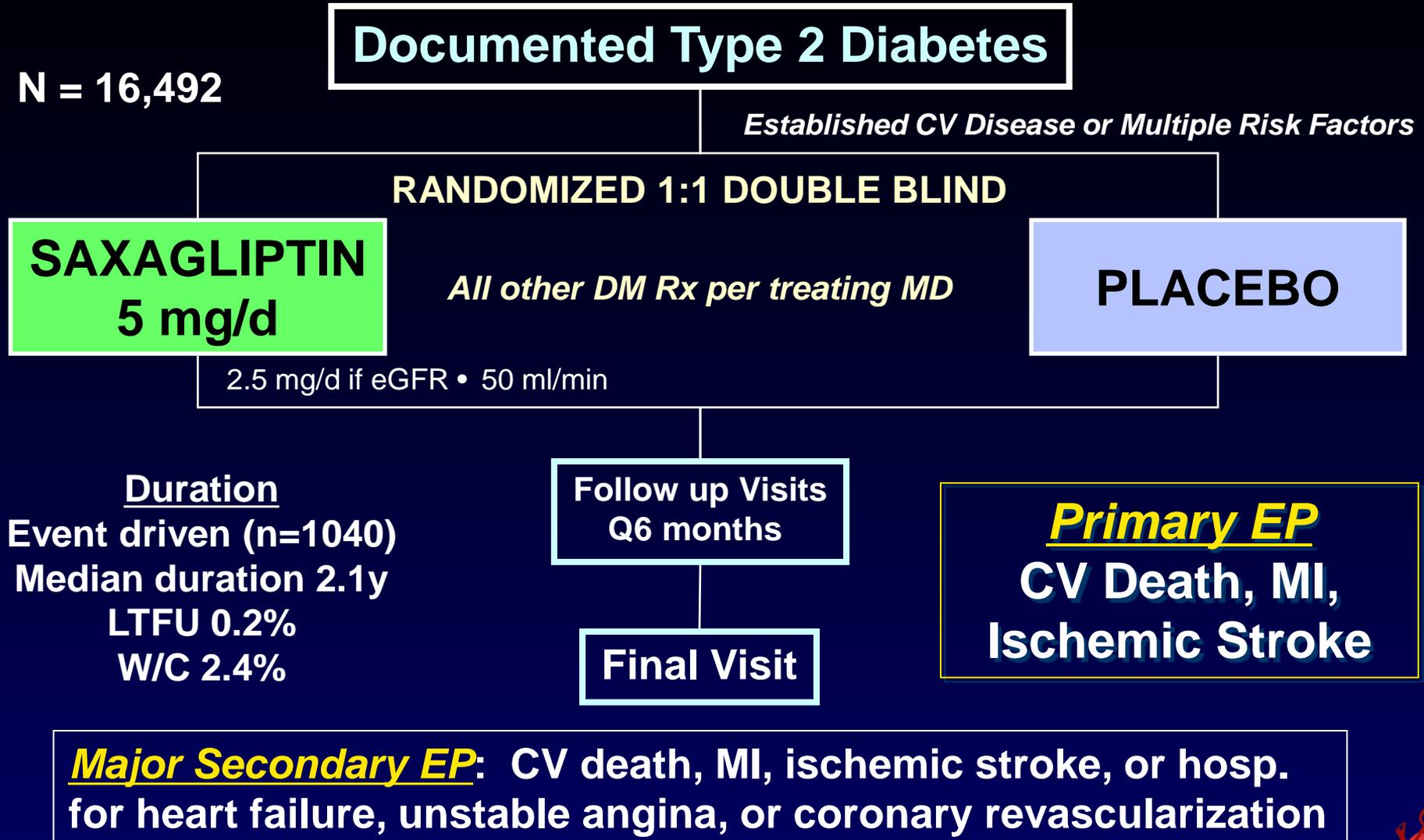
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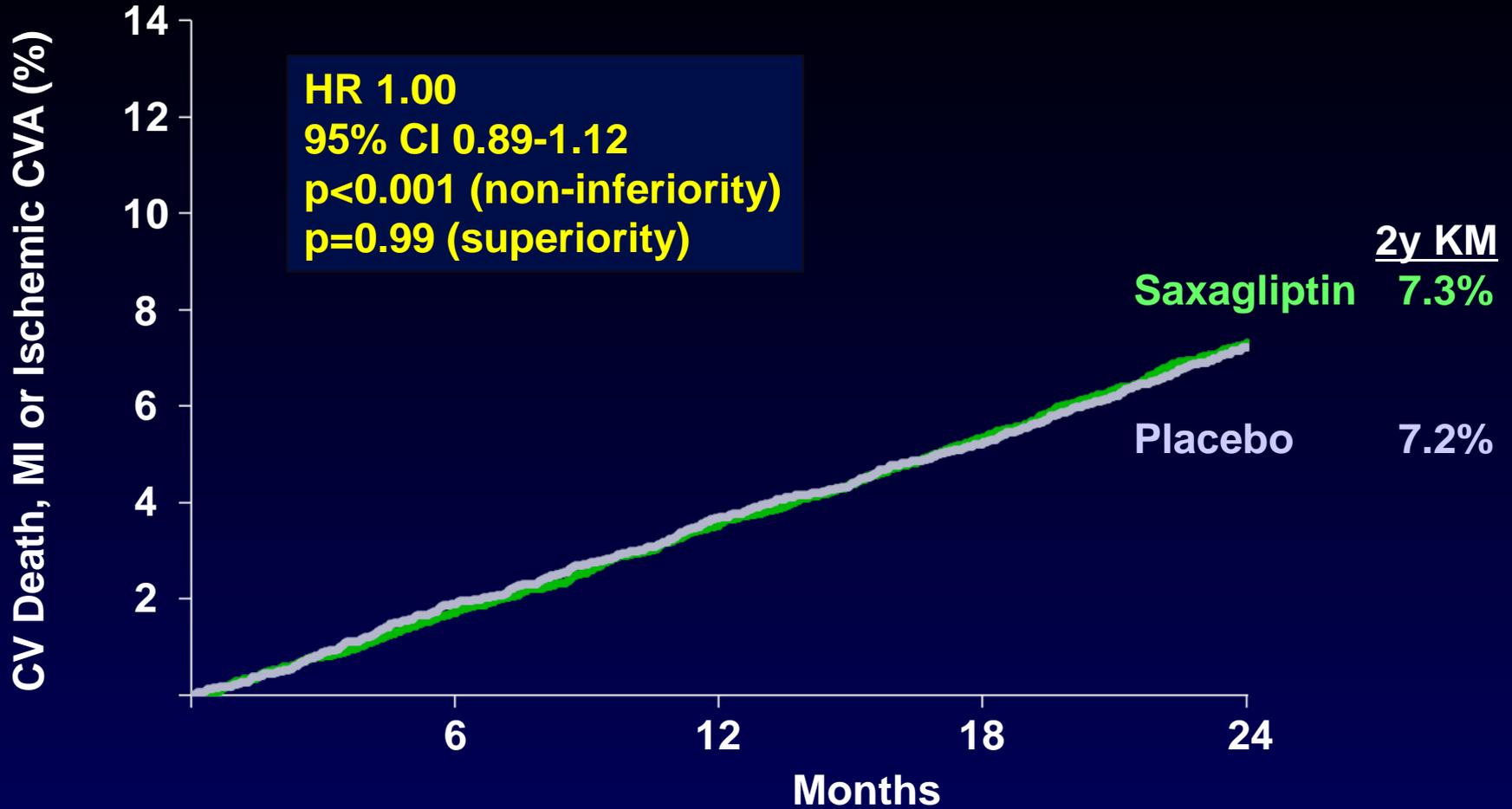
Primary Objective

- To determine whether when added to background therapy, **saxagliptin** would be non-inferior to **placebo** for the composite endpoint of CV death, non-fatal MI, or non-fatal ischemic stroke (Upper 95% CI of HR < 1.3).
- And if non-inferiority were met, to determine if **saxagliptin** would be superior to placebo.

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Primary Endpoint



Placebo	8212	7983	7761	7267	4855
Saxagliptin	8280	8071	7836	7313	4920

Conclusions

- When added to standard of care in patients with T2DM at high CV risk, **saxagliptin** neither reduced nor increased the risk of the primary composite endpoint of CV death, MI, or ischemic stroke.

- **In addition, saxagliptin:**
 - Improved glycemic control
 - Decreased the need for insulin and other diabetes medications
 - Increased hypoglycemic events, but not hospitalization for hypoglycemia
 - Prevented progression of microalbuminuria
 - Did not increase risk of pancreatitis or pancreatic cancer

Conclusions (Heart Failure)

- **The higher incidence of hospitalization for heart failure was unexpected, but it was a pre-defined, adjudicated endpoint.**
- **It merits further evaluation given the history of other diabetic agents and heart failure.**
- **Additional analyses are ongoing, and preliminary data suggest that the risk is highest in those with elevated baseline clinical risk for heart failure and/or elevated BNP levels.**

- **SAVOR-TIMI 53 highlights the importance of performing large trials with clinical cardiovascular endpoints for diabetes drugs.**
- **Further research is needed to explore the relationship between HbA1c and cardiovascular outcomes.**