# Objectives and End Points of EXAMINE

- **Primary objective**: To demonstrate that major CV event rates are not higher with alogliptin than with placebo in type 2 diabetes patients with recent ACS who are receiving standard of care for diabetes and secondary CV prevention
  - **Primary end point**: composite of first occurrence of CV death, nonfatal MI, and nonfatal stroke

  **Secondary Objectives:**

  **Superiority assessment:** If non-inferiority proven, to demonstrate that major CV event rates were lower on alogliptin than with placebo

  **Secondary end point:** Evaluate the time from randomization to the first occurrence of the expanded MACE:
  - Composite of CV death, nonfatal MI, nonfatal stroke, and urgent revascularization due to UA
- **Major exploratory end points**: all CV deaths, all-cause mortality

Abbreviations: ACS, acute coronary syndrome; CV, cardiovascular; MI, myocardial infarction; UA, unstable angina.

# DECLARATION OF INTEREST

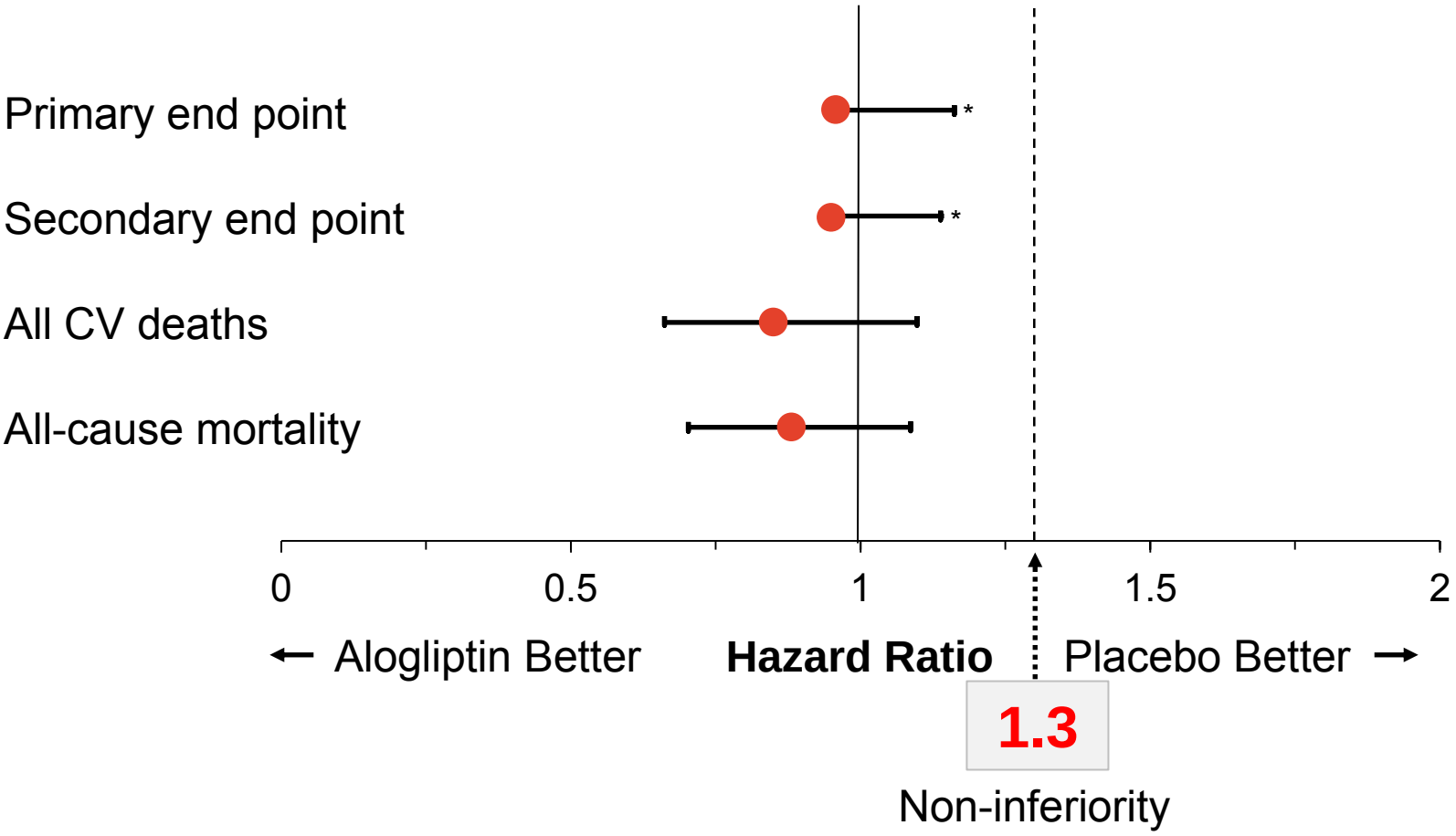
- Consulting/Royalties/Owner/ Stockholder of a healthcare company

# Study Patients

- Diagnosis of type 2 diabetes and receiving antihyperglycemic therapy (single or combination therapies)
- Acute coronary syndrome* within 15 to 90 days before randomization
- Receiving local standard of care for type 2 diabetes care and secondary CV prevention (excluded were DPP-4 inhibitors and GLP-1 agonists)
- Patients with unstable cardiovascular conditions or those on dialysis within 14 days of planned randomization were excluded

* Myocardial infarction or hospitalized unstable angina

# Non-Inferiority Met for All End Points




* One-sided repeated CI using alpha=0.01.

# Summary of All Major Findings

- Rates of major adverse cardiovascular events were similar with alogliptin compared with placebo in patients with type 2 diabetes and recent acute coronary syndromes
- This observation occurred in the following context:
  - Significantly lower $HbA_{1C}$ level (–0.36%) with alogliptin
  - High overall CV event rate (11% over the median follow-up of 18 months)
  - High levels of standard of care for both diabetes and cardiovascular prevention
- Outcomes were similar for the secondary end point (composite of CV death, nonfatal MI, nonfatal stroke, urgent revascularization due to UA)

# Summary (2)

- Rates of cardiovascular and all-cause mortality were similar in the alogliptin and placebo groups
- Similar rates of withdrawal due to adverse events in the alogliptin and placebo groups
- Other adverse events of interest
  - No differences between alogliptin and placebo groups in
    - Incidence of Hypoglycemia
    - Reported malignancies ( including pancreatic cancer)
    - Renal function
  - Low and similar frequencies of acute and chronic pancreatitis were observed

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ORIGINAL ARTICLE

# Alogliptin after Acute Coronary Syndrome in Patients with Type 2 Diabetes

William B. White, M.D., Christopher P. Cannon, M.D., Simon R. Heller, M.D., Steven E. Nissen, M.D., Richard M. Bergenstal, M.D., George L. Bakris, M.D., Alfonso T. Perez, M.D., Penny R. Fleck, M.B.A., Cyrus R. Mehta, Ph.D., Stuart Kupfer, M.D., Craig Wilson, Ph.D., William C. Cushman, M.D., and Faiez Zannad, M.D., Ph.D., for the EXAMINE Investigators*

## Conclusion:

In patients with type 2 diabetes and recent acute coronary syndrome, major adverse cardiovascular event rates for the DPP-4 inhibitor alogliptin were not increased compared with placebo