



Brigham and Women's Hospital
Founding Member, Mass General Brigham



Estimated Lifetime Benefits Of Finerenone On Cardiorenal Morbidity And Mortality In Patients With Chronic Kidney Disease And Type 2 Diabetes

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#AHA25



American
Heart
Association.

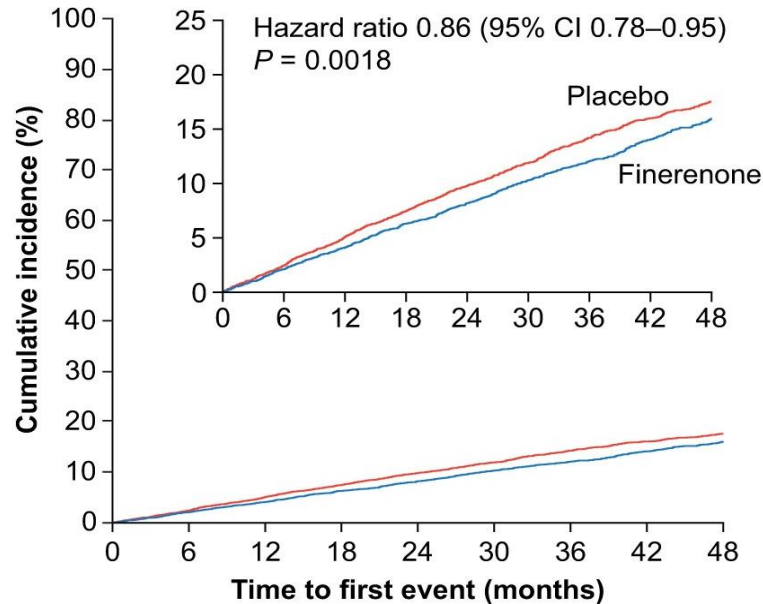
DISCLOSURES

- JWO reports research support from the National Institutes of Health (5T32HL007604-39 and L30HL175757) and has served on advisory boards or had speaker engagements with Corcept Therapeutics
- The FIDELIO-DKD and FIGARO-DKD trials were sponsored by Bayer AG

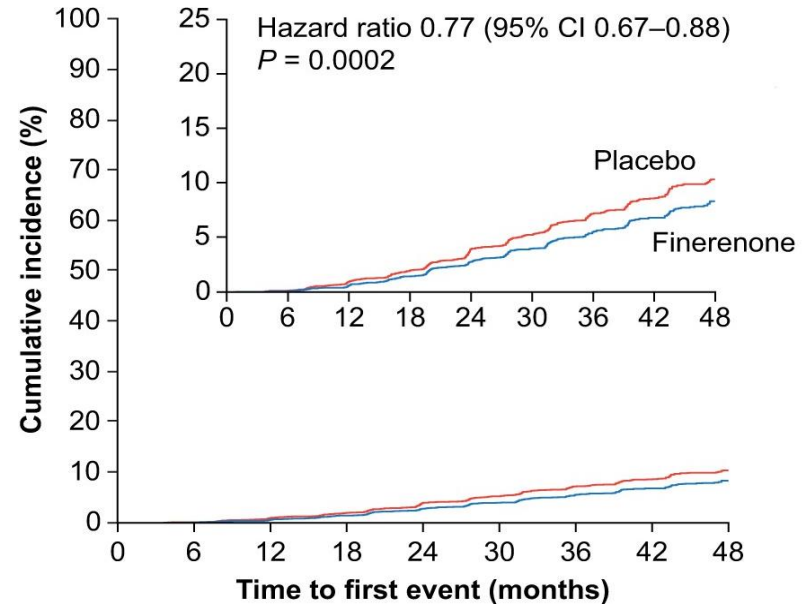
BACKGROUND

- Cardiovascular and kidney outcomes with finerenone in FIDELITY:

A Composite cardiovascular outcome



B eGFR $\geq 57\%$ composite kidney outcome



STUDY POPULATION

- **FIDELITY**: a prespecified participant-level pooled analysis of two complementary, global, randomized trials (n=12,990) that evaluated finerenone vs. placebo in persons with CKD and type 2 diabetes

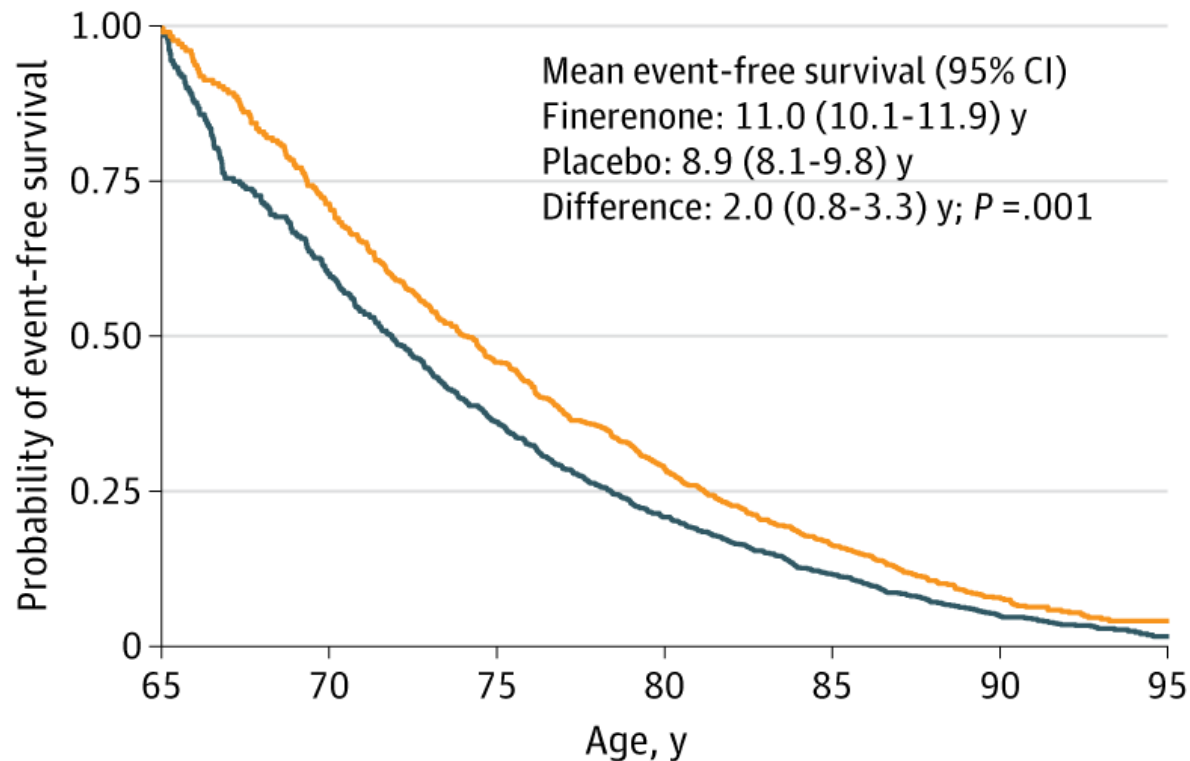


- Recruitment: 2015-2018
- Population: CKD and T2D, with albuminuria
- Primary outcome: kidney failure, sustained eGFR decrease $\geq 40\%$, or renal death

- Recruitment: 2015-2018
- Population: CKD and T2D, with albuminuria
- Primary outcome: CV death, non-fatal MI, non-fatal stroke, or HF hospitalization

METHODS

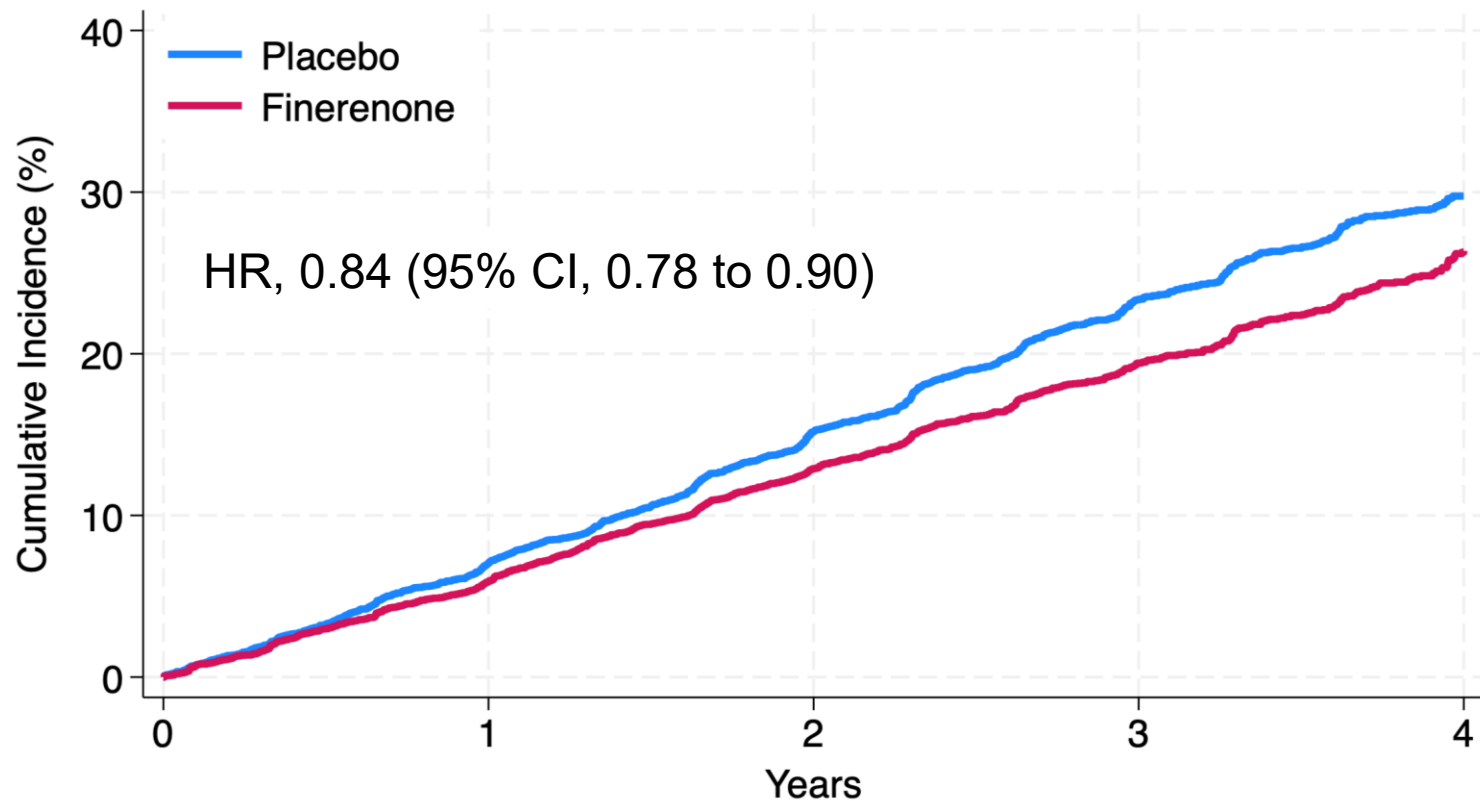
Modeling Event-Free Survival Using Validated, Age-Based Actuarial Methods in FINEARTS-HF



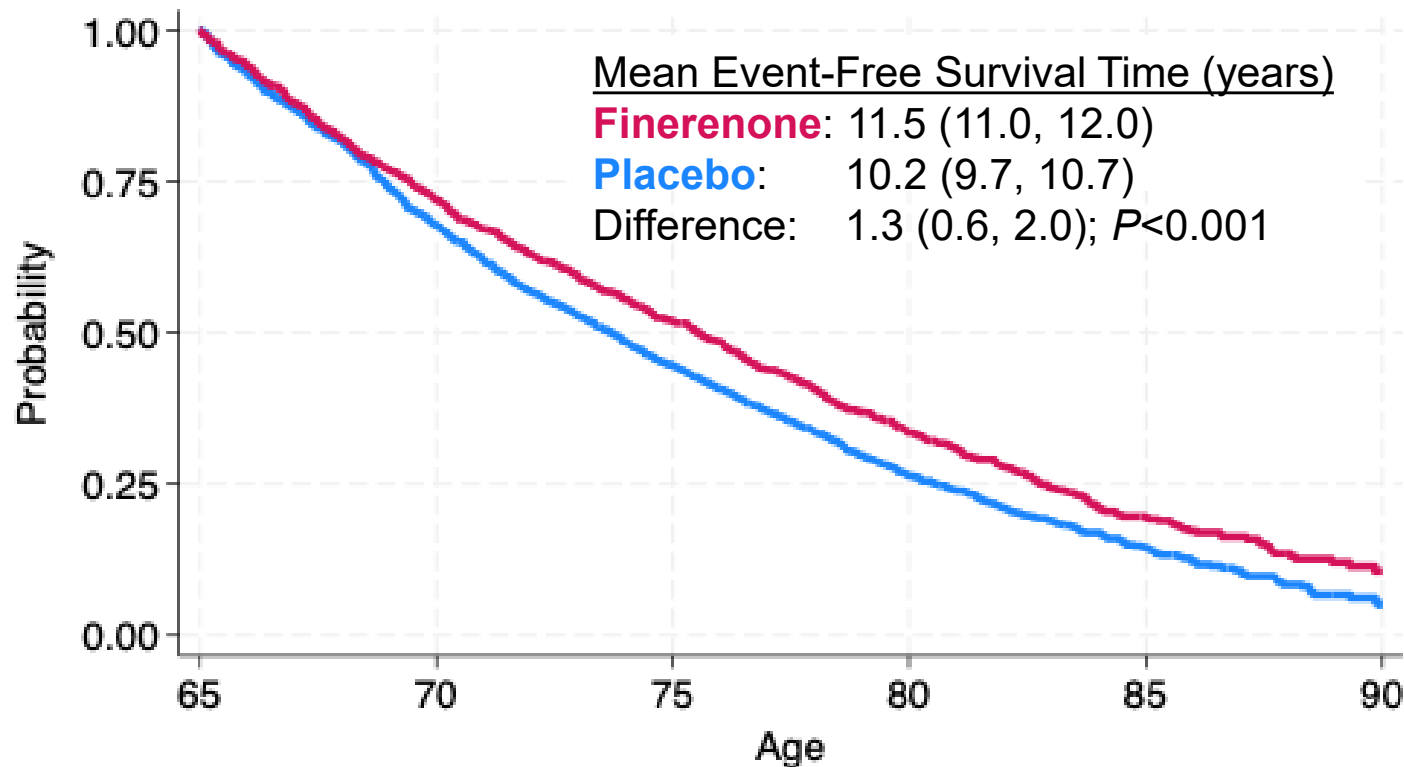
METHODS

- **Cardiorenal composite outcome:** all-cause death & the non-fatal components of the prespecified cardiovascular (HF hospitalization, MI, or stroke) and kidney (sustained $\geq 57\%$ \downarrow in eGFR or kidney failure) endpoints
 1. Estimated residual event-free survival at all enrolled ages, separately in the finerenone and placebo arms
 2. Constructed lifetime event-free survival curves by randomized treatment, and projected event-free survival to a maximum age of 90
 3. Estimated projected lifetime gains in event-free survival at all ages between 50 and 80 years

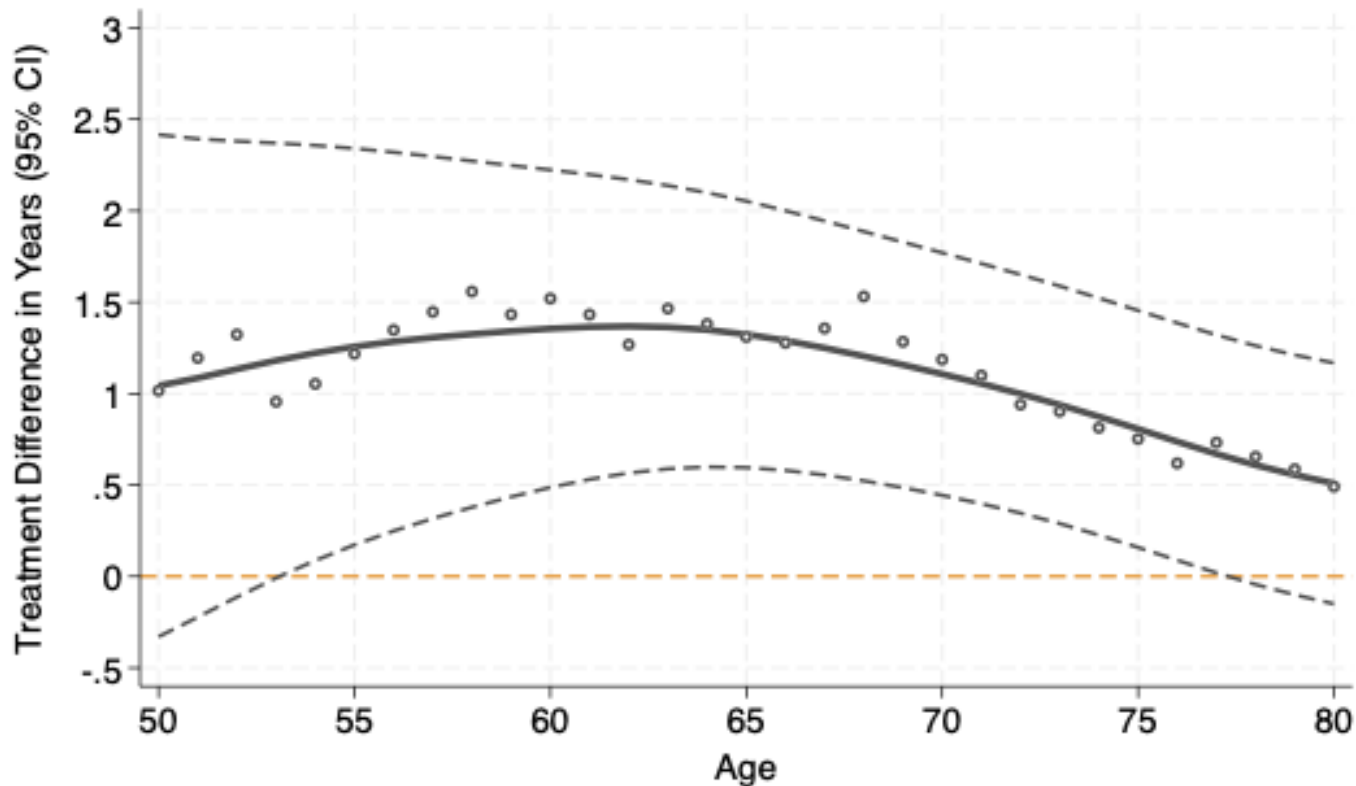
COMPOSITE CARDIORENAL EVENTS IN FIDELITY



PROJECTED EVENT-FREE SURVIVAL AFTER AGE 65 YEARS



LIFETIME GAINS IN EVENT-FREE SURVIVAL, BY BASELINE AGE



DISCUSSION

- In this FIDELITY analysis, meaningful gains in cardiorenal event-free lifespan with finerenone were estimated across a broad age range
- These time-based estimates provide a complementary and digestible perspective of expected treatment effect when considered alongside the findings of pivotal clinical trials
- Key limitation
 - Longitudinal adherence may be different in non-trial settings due to multiple factors, including access, tolerability, and cost

CONCLUSIONS

Treatment with finerenone is projected to afford clinically relevant long-term gains in survival free from cardiorenal morbidity and mortality

These findings reinforce its role as a key component of guideline-directed medical therapy for persons with CKD and type 2 diabetes

THANK YOU



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