

**ESC 31 August 2015**  
**Hot Line III - Diabetes mellitus/Pharmacology**

**Evaluation of LIXisenatide in  
Acute Coronary Syndrome (ELIXA)**

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**ELIXA Trial Executive Committee:**  
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**Jeffrey Probstfield, Matthew Riddle, Scott Solomon, Jean-Claude Tardif**

on behalf of the ELIXA Investigators

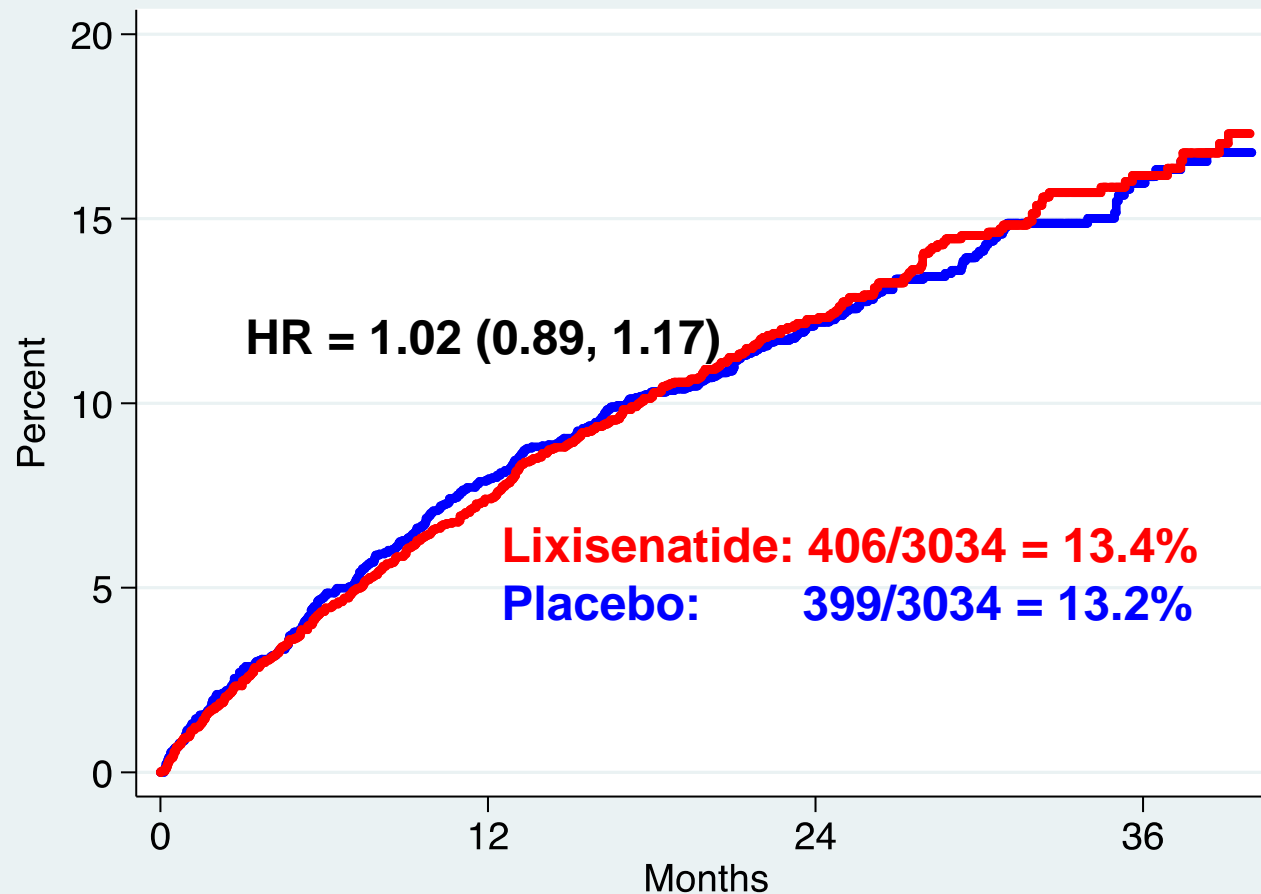
ClinTrials.gov NCT01147250

# DECLARATION OF INTEREST

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



# 1° Outcome (CV Death, MI, Stroke or UA)



Number at risk

Placebo 3034

Lixisenatide 3034

2759

2785

1566

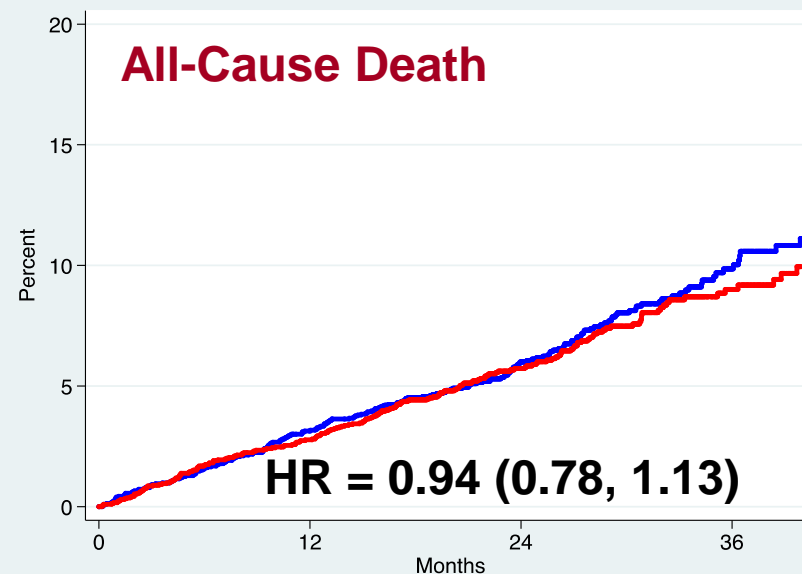
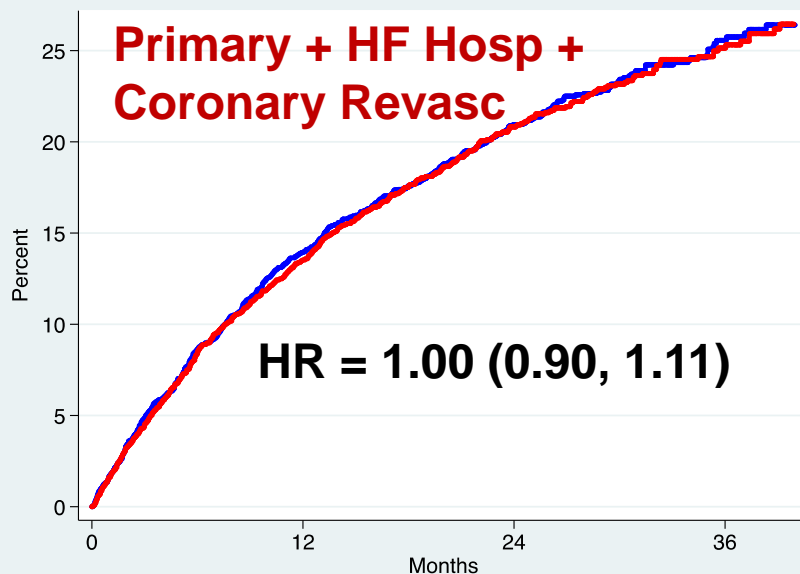
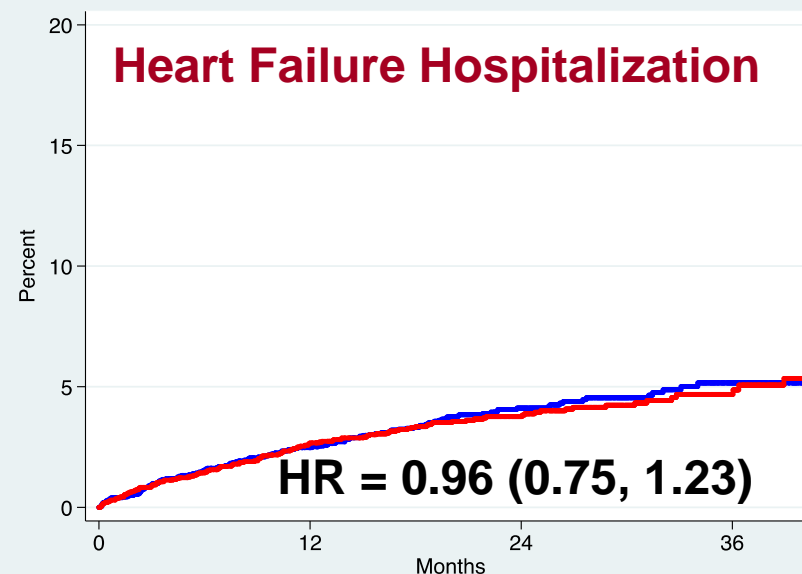
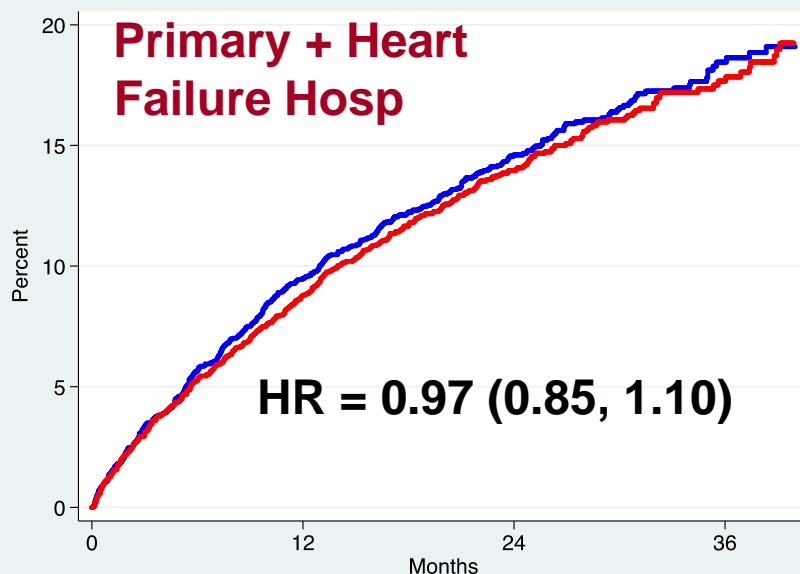
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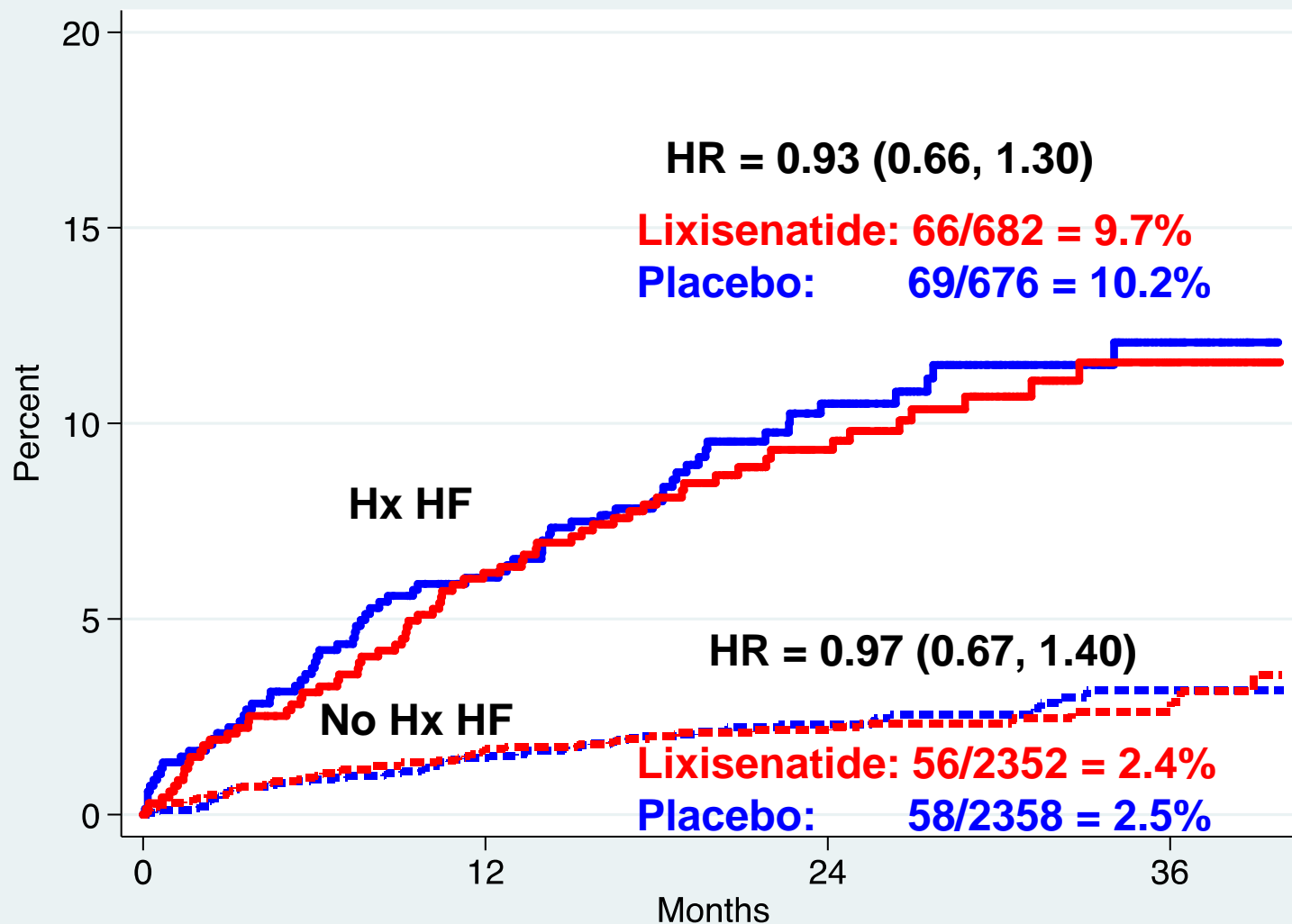
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# Lixisenatide & CV Outcomes



# Heart Failure Hospitalization (by History of HF)



# ELIXA Summary

- Demonstrates CV safety of lixisenatide (as defined by FDA Guidance), but not superiority in reducing CV events
- Additional analyses indicate safety with respect to heart failure events as well as death
- Neutral effects seen across wide spectrum of heart failure risk



## Results:

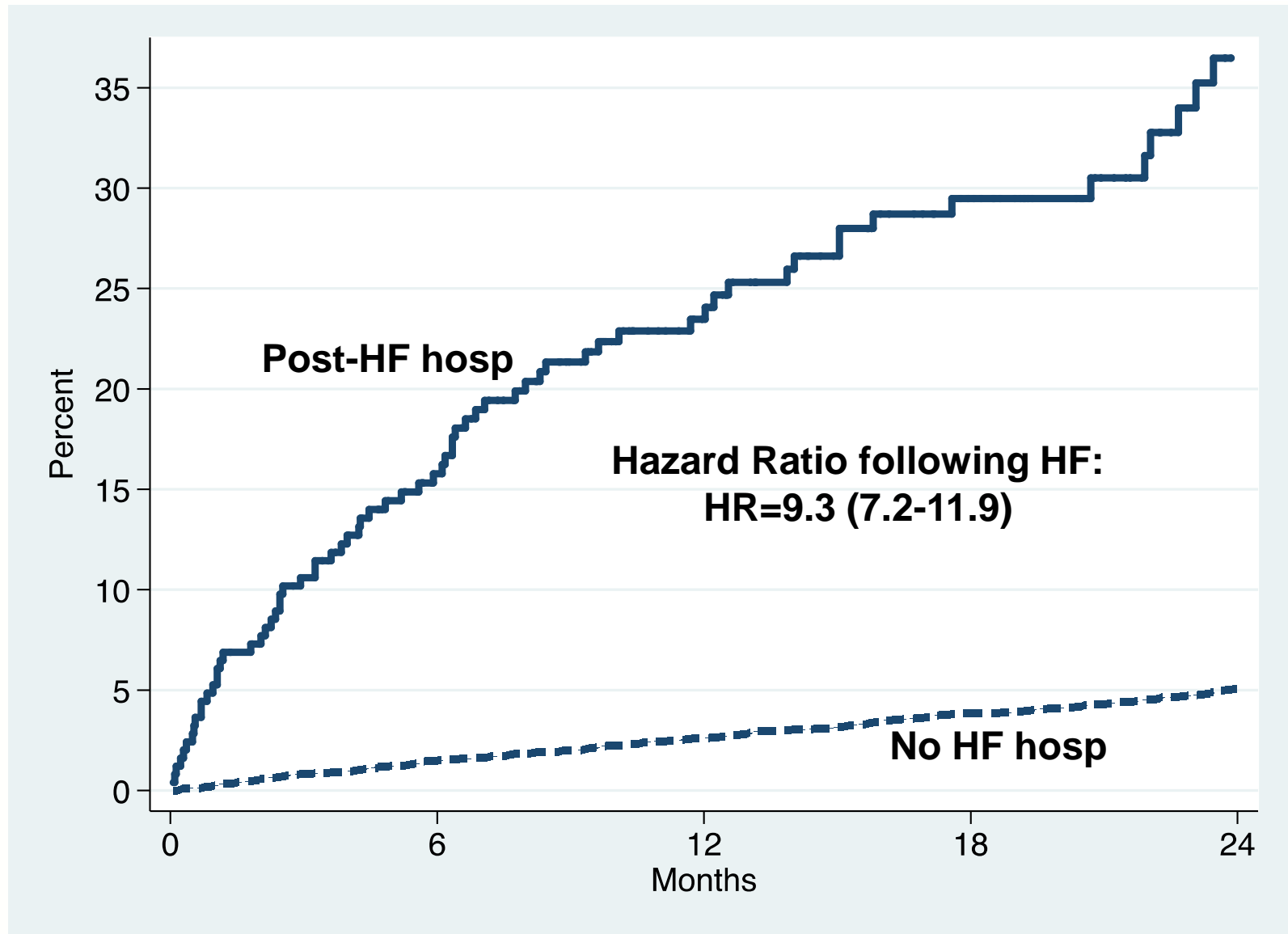
### Biomarker changes with lixisenatide vs placebo

- 1) **HbA1c (absolute value) was 0.27% lower\***  
*(with similar hypoglycemia events)*
- 2) **Weight change was 0.7kg less\***  
*(with more frequent discontinuation due to GI complaints 4.9% vs. 1.2%\* )*
- 3) **SBP was 0.8 mmHg less\***
- 4) **Albuminuria increased less, 24% vs 34%\***
- 5) **Heart rate was increased 0.4 bpm\***

\*  $p < 0.05$



# Mortality\* following HF Hosp



\*76 of 434 deaths (18%) in ELIXA occurred post-HF hosp

# Clinical Outcomes by BNP\*



BNP Quartile	Primary Outcome	Heart Failure	CVD + HF
Incidence Rate (per 100 patient-years)			
1 ( $\leq 50$ pg/mL)	3.2	0.2	0.7
2 (51-107 pg/mL)	4.4	1.0	1.8
3 (108-219 pg/mL)	5.7	1.6	3.0
4 ( $\geq 220$ pg/mL)	13.4	5.2	10.8

\*no significant interactions between BNP quartile and treatment effect HR



# CV Death + Heart Failure Hospitalization (by history of HF)

