Third Heart Failure Clinical Trialists Workshop

12 – 13 February 2012, Nice – France

HEART FAILURE ENDPOINTS DEFINITION IN HEART FAILURE AND NON-HEART FAILURE OUTCOME TRIALS

Chairmen: Faiez Zannad and Piotr Ponikowski

Sunday 12th February

Endpoints in heart failure trials

8.00 - 10.00

Heart failure hospitalization

Chairperson: Kenneth Dickstein

i. Are all heart failure hospitalizations worsening heart failure?
Speaker: Tiny Jaarsma

ii. Validation with raised BNP?

iii. Contribution of thrombo-embolic events
Speaker: Mihai Gheorghiade

Should we start adjudicating non-hospitalized heart failure events?

i. ER visits? Outpatient clinic?? GP visits???
Speaker: Scott Solomon
Discussant: Gerasimos Filippatos

ii. ICD shocks/using devices to detect arrhythmias?
Speaker: Kenneth Stein
Discussant: Frank Ruschitzka

10.00 - 10.20 Coffee Break

10.20 - 12.20

And what if we ask patients? Symptoms, QOL and PROs

Chairperson: Tiny Jaarsma

i. Dyspnoea in acute heart failure trials.
Speaker: Marvin Konstam
Discussant: Marco Metra

ii. QOL and PRO measures. Do we have the right instruments?
Speaker: Inger Ekman
Discussant 1: Luigi Tavazzi
Discussant 2: Karl Swedberg

Unconventional endpoints: Packer, Patient journey, others

Speaker: Burkert Pieske
Discussant: John Cleland

Regulatory view point:

Giuseppe Rosano, Norman Stockbridge

12.20-13.30 Lunch

13.30 - 15.40

Mortality and Composite endpoints

Chairperson: Luigi Tavazzi

Dead is dead?

i. All cause death vs. Cause specific death
ii. Modes of death. How sudden is sudden death?

Speaker: John Cleland
Discussant: Piotr Ponikowski
Regulatory view point: Norman Stockbridge

Combined endpoints and other original composites

Speaker: Jay Cohn
Discussant: Roger Mills

How to deal with recurrent morbid events in event driven trials

Speaker: Stuart Pocock
Discussant: Gordon Murray

Regulatory view point:

Gonzalo Calvo, Norman Stockbridge, Angeles Alonso

15.40 - 16.00 Coffee Break

16.00- 17.30

Acute HF and HFPEF trial endpoints

Chairperson: Frank Ruschitska

Should endpoints in HF-PEF be different than in HF-REF?

Speaker: Scott Solomon
Discussant: Karl Swedberg

Should endpoints in acute heart failure be different than in chronic heart failure?

Speaker: Paul Armstrong
Discussant: Aldo Maggioni

Regulatory viewpoint:

Bram Zuckerman *via conference call*

Monday February 13th

8.00 - 9.30

Secondary and safety endpoints:

Chairperson: Stefan Anker

Non heart failure secondary efficacy endpoints. Definition issues.

i. Atrial fibrillation

i. New onset diabetes

Speaker: Aldo Maggioni
Discussant: Luigi Tavazzi

Safety endpoints in heart failure trials

i. Mortality as a safety endpoint. Statistical consequences
ii. What to pre-specify, adjudicate?
iii. Renal function

Speaker: Adrian Hernandez
Discussant: Adrian Voors

9.30-9.50 Coffee Break

9.50 - 11.00

Time issues. When should we stop the counter?

Chairperson: John Cleland

i. Fixed FU time vs. event driven trial termination
ii. Monitoring events during the trial. Interim analyses and early termination issues

Speaker: Joerg Koglin
Discussant 1: Stuart Pocock
Discussant 2: Faiez Zannad

Regulatory viewpoint:

Angeles Alonso, Norman Stockbridge

11.00 -12.00

The case of device and cell therapy trials

Chairperson: Paul Armstrong

Speaker: Ileana Pina
Discussant: Stefan Anker
Regulatory view point: Bram Zuckerman

12.00 -13.00 Lunch Break

Heart failure as an endpoint in non heart failure trials

13.00 -15.00

Chairperson: Piotr Ponikowski

Shouldn't heart failure as a specific endpoint be pre-specified in all cardiovascular prevention trials?

Speaker: Faiez Zannad
Discussant: Mike Domanski

How to define new onset heart failure as an efficacy/safety endpoint? Time for harmonization?

i. Overview of heart failure definitions in CV prevention trials
ii. The case of heart failure endpoints in CAD, ACS trials, Diabetes trials, CKD and dialysis CV prevention trials

Speaker: Luis Ruilope

Discussant: Gordon Murray

Regulatory view point: Gonzalo Calvo, Norman Stockbridge

15.00 -16.30

Consensus building

Chairperson: Faiez Zannad

Consensus: Definition of heart failure events as an outcome in heart failure and non heart failure outcome trials

16.30 Adjourn

Faculty

Europe

1. Piotr Ponikowski (Wroclaw, PL)
2. Stefan Anker (Berlin, DE)
3. John Cleland (Kingston upon Hull, UK)
4. Inger Ekman (Gothenburg, SE)
5. Tiny Jaarsma (Linkoping, SE)
6. Aldo Maggioni (Florence, IT)
7. Alexandre Mebazaa (Paris, FR)
8. Stuart Pocock (London, UK)
9. Frank Ruschitzka (Zurich, CH)
10. Karl Swedberg (Gothenburg, SE)
11. Luigi Tavazzi (Cotignola, IT)
12. Faiez Zannad (Nancy, FR)
13. Kenneth Dickstein (Stavanger, NO)
14. Marco Metra (Brescia, IT)
15. Luis Ruilope (Madrid, ES)
16. Adriaan Voors (Groningen, NL)
17. Burkert Pieske (Graz, AT)
18. Gerasimos Filippatos (Athens, GR)
19. Gordon Murary (Edinburgh, UK)

Americas

20. Paul Armstrong (Edmonton, CA)
21. Jay Cohn (Minneapolis, US)
22. Adrian Hernandez (Durham, US)
23. Scott Solomon (Boston, US)
24. Marvin Konstam (Boston, US)
25. Mihai Gheorghiade (Chicago, US)
26. Michael Domanski (New York, US)
27. Ileana Pina (Cleveland, US)

Industry

28. Joerg Koglin (MSD, US)
29. Ken Stein (Boston Scientific, US)
30. Scott Wasserman (Amgen, US)
31. Andrew Zalewski (Novartis, US)
32. Holger Woehrle (ResMed, DE)
33. Roger Mills(Johnson & Johnson, US)
34. Stuart Kupfer (Takeda, US)
35. Christina Nowack (Bayer, DE)

Regulatory

EMEA

36. Angeles Alonso (Madrid, ES)
37. Gonzalo Calvo (Madrid, ES)
38. Giuseppe Rosano (Rome, IT)

FDA

39. Norman Stockbridge (FDA, US)
40. Bram Zuckerman (FDA, US) via conference call