Workshop on HEART FAILURE

Rome, November 24-25, 2013

In collaboration with:

European Medicines Agency (EMA)

Heart Failure Association (HFA)
General Information

Workshop Venues
Sunday, November 24: Hotel delle Nazioni (Via Poli, 6 - Rome)
Monday, November 25: AIFA Headquarters (Via del Tritone, 181 - Rome)

Scientific and Organizing Coordinator
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**Sunday, November 24**
*Hotel delle Nazioni - Campigli Room*

17.00

Welcome by the Giovanni Lorenzini Medical Foundation

Introduction to the Meeting

**Guido Rasi** (UK), **Luca Pani** (I), **Sergio Pecorelli** (I)
Unmet needs: what can be done? The point of view of the regulatory agencies

**Giuseppe Rosano** (I)
Purpose and goals of the next day’s session

**Q & A and Discussion**
*All Participants*

19.00

Closing of the session

**Monday, November 25**
*AIFA - Room 2-3-4*

8.30 - 8.40

Registration

*Chair: Luca Pani* (I)

8.45 - 9.00

**Luca Pani** (I), **Guido Rasi** (UK)
Introductory remarks

**Stefan D. Anker** (G)
Heart failure today: where we are, where we should be

**Q & A and Discussion**
*All Participants*
UNMET NEEDS, OPPORTUNITIES

Chair: Andrew J. Stewart Coats (UK and Australia)

9.50 - 10.00
Claudio Ceconi (I)
Biomarkers in heart failure: limits and opportunities

10.00 - 10.10
Krishna Prasad (UK)
What do regulators expect from HF trials and how guidelines can help

10.10 - 10.20
Ameet Nathwani (CH)
The challenges of developing drugs in AHF: an industry perspective

10.20 - 10.30
Stefan D. Anker (G)
The need for better endpoints: the clinicians’ view

10.30 - 10.40
Paolo D. Siviero (I)
Reimbursement policies in Europe: values and limits

10.40 - 11.00
Break

11.00 - 11.20
Andrew J. Stewart Coats (UK and Australia)
Summary of the presented unmet needs and opportunities

11.20 - 13.00
Q & A and Discussion
Chairs: Marco Metra (I) and Paolo D. Siviero (I)
All participants
Mitja Lainscak (SLO)
Claudio Mori (CH)

13.00 - 14.00
Lunch
THE WAY FORWARD

Chairs: Mihai Gheorghiade (USA), Mitja Lainscak (SLO)

14.00 - 14.10
Mihai Gheorghiade (USA)
How to better harmonize clinical needs, innovative trials/ methods

14.10 - 14.20
Andrew J. Stewart Coats (UK and Australia)
Clinical view of solutions: how to effectively resolve these perceived conflicts

14.20 - 14.30
Giuseppe Rosano (I)
Regulatory endpoints

14.30 - 14.40
Nancy Cook-Bruns (G)
What are the expectations of the industry?

14.40 - 14.50
Laura Fregonese (UK)
Biomarker qualification programs

14.50 - 15.00
Americo Cicchetti (I)
What will be worth paying for

15.00 - 15.10
Mihai Gheorghiade (USA) and Mitja Lainscak (SLO)
Summary of the presented perspectives

15.10 - 16.15
Q & A and Discussion
Chairs: Stefan D. Anker (G) and Krishna Prasad (UK)
All participants
Simona Montilla (I)

16.15 - 16.30
Sergio Pecorelli (I)
Closing remarks
List of the Participants

Stefan D. Anker  
Professor of Cardiology & Cachexia Research  
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President, Heart Failure Association

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Secretary General & CEO  
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