



*Agenzia Italiana del Farmaco*

**AIFA**

# **Workshop on HEART FAILURE**

Rome, November 24-25, 2013

*In collaboration with:*

**European Medicines Agency (EMA)**



**Heart Failure Association (HFA)**

FONDAZIONE  
GIOVANNI LORENZINI  
MILAN, ITALY



GIOVANNI LORENZINI  
MEDICAL FOUNDATION  
HOUSTON, TX, USA

## *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**

**Fondazione Giovanni Lorenzini Medical Science Foundation**

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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

9.00 - 9.25

**Stefan D. Anker** (G)

Heart failure today: where we are, where we should be

9.25 - 9.45

**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 - 11.10

*Break*

11.10 - 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 Gheorghide (USA), Mitja Lainscak (SLO)*

14.00 - 14.10

**Mihai Gheorghide** (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 Gheorghide** (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  
Applied Cachexia Research  
Department of Cardiology  
Charité, Campus Virchow-Klinikum  
Berlin (Germany)  
President, Heart Failure Association

## **Paola Castellani**

Head of Clinical Development  
Medical Affairs and Patient Advocacy  
Region Europe  
Novartis Pharma  
Basel (Switzerland)

## **Claudio Ceconi**

Department of Medical Sciences  
Division of Cardiology  
University of Ferrara  
Ferrara (Italy)

## **Americo Cicchetti**

Director Graduate School of Health  
Economics and Management  
Catholic University of Sacred Heart  
Rome (Italy)

## **Alessandro Cirrincione**

Pricing and Market Access  
Global Director  
Vifor Pharma  
Glattbrugg (Switzerland)

## **Andrew J. Stewart Coats**

Academic Vice-President, Monash  
University, Australia and University of  
Warwick, UK  
Director of the Monash Warwick Alliance  
Warwick (UK) and Melbourne (Australia)

## **Nancy Cook-Bruns**

Head Cardiovascular Group  
Global Clinical Development  
Bayer Pharma Aktiengesellschaft  
Elberfeld (Germany)

## **Emanuela Folco**

Secretary General & CEO  
Fondazione Giovanni Lorenzini  
Medical Science Foundation  
Milan (Italy) and Houston (USA)

## **Laura Fregonese**

Scientific Administrator  
European Medicines Agency (EMA)  
London (UK)

## **Mihai Gheorghiade**

Professor of Medicine and Surgery  
Director of Experimental Therapeutics  
Center for Cardiovascular Innovation  
Northwestern University Feinberg  
School of Medicine  
Chicago (USA)

## **Roland Gordon-Beresford**

Sr Director Regulatory Affairs and  
Intellectual Property  
Cardio3 BioSciences S.A.  
Mont-Saint-Guibert (Belgium)

## **Christian Homsy**

Chief Executive Officer  
Cardio3 BioSciences S.A.  
Mont-Saint-Guibert (Belgium)

## **Mitja Lainscak**

Associate Professor of Internal Medicine  
University Clinic Golnik  
Division of Cardiology  
Golnik (Slovenia)  
Heart Failure Association, Patient Care  
Committee

***Guy Lerebours***

Medical and Scientific Director  
Cardiovascular Research and  
Development Servier  
Neuilly-sur-Seine (France)

***Susan Longman***

Head Drug Regulatory Affairs Europe and  
Greater China  
Novartis Pharma AG  
Basel (Switzerland)

***Patricia Maillere***

Director Worldwide Regulatory Affairs  
Servier  
Neuilly-sur-Seine (France)

***Marco Metra***

Department of Medical and Surgical  
Specialities, Radiological Sciences and  
Public, University of Brescia  
Brescia (Italy)

***Markus Meyer***

Cardioentis Ltd  
Steinhausen (Switzerland)

***Simona Montilla***

Health Technology Assessment Expert  
Office for Pharmaceutical Policy  
Italian Medicines Agency (AIFA)  
Rome (Italy)

***Claudio Mori***

Medical Affairs TA Cardio&New Indication  
Medical Lead MA Studies  
Vifor Pharma  
Glattbrugg (Switzerland)

***Ameet Nathwani***

Franchise Head Critical Care  
Novartis Pharma AG  
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Director General  
Italian Medicines Agency (AIFA)  
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***Sergio Pecorelli***

President  
Italian Medicines Agency (AIFA)  
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***Andrea Peracino***

Vice President  
Fondazione Giovanni Lorenzini  
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Milan (Italy) and Houston (USA)

***Krishna Prasad***

Medicines and Healthcare Products  
European Medicines Agency (EMA)  
London (UK)

***Guido Rasi***

Executive Director  
European Medicines Agency (EMA)  
London (UK)

***Giuseppe Rosano***

Department of Medical Sciences, IRCCS  
San Raffaele, Rome  
Rome (Italy)

***Olga Santiago***

Executive Global Program Head  
Heart Failure  
Novartis Pharmaceutical Corporation  
East Hanover (USA)

***Paolo D. Siviero***

Head, Economic Strategy and  
Pharmaceutical Policy  
Italian Medicines Agency (AIFA)  
Rome (Italy)

***Mary Lou Wratten***

Medical Director  
Thermo Fisher (B.R.A.H.M.S Italia)  
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[www.lorenzinifoundation.org](http://www.lorenzinifoundation.org)