CVCT

8th Global CardioVascular Clinical Trialists Forum

PARIS CVCT 2011

Course Directors: Faiez ZANNAD, Nancy - FRA
Bertram PITT, Ann Arbor - USA
Christopher O'CONNOR, Durham - USA

2-3 DECEMBER 2011

www.globalcvctforum.com

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Final Program and Abstracts

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ROSENSON Robert, New York, USA
ROSSIGNOL Patrick, Nancy, FRA
RUILOPE Luis Miguel, Madrid, ESP
SABBAH Hani, Detroit, USA
SCHERNTHANER Guntram, Vienna, AUT
SEVER Peter, London, GBR
SICA Domenic, Richmond, USA
SIMON Tabassome, Paris, FRA
SLEIGHT Peter, Oxford, GBR
STAELS Bart, Lille, FRA
STOSCHITZKY Kurt, Graz, AUT
STRUTHERS Alan, Dundee, GBR
SWEDBERG Karl, Gothenburg, SWE
SWYNGHEDAUW Bernard, Paris FRA
TAWAKOL Ahmed, New York, USA
TAVAZZI Luigi, Cotignola, ITA
TEDGUI Alain, Paris, FRA
TOUBOUL Pierre Jean, Paris, FRA
VERHEUGT Freek, Amsterdam, NDL
VOORS Adrian, Groningen, NDL
WARNOCK David G., Birmingham, USA
WAEBER Bernard, Lausanne, CHE
WOOD David, London, GBR
ZANNAD Faiez, NANCY, FRA

NHLBI, NIH

GELLER Nancy, Bethesda, USA
GORDON David, Bethesda, USA
LAUER Michael S., Bethesda, USA
MASCETTE Alice, Bethesda, USA
ROSENBERG Yves, Bethesda, USA

EMEA

ALONSO Angeles, Madrid, ESP
CALVO Gonzalo, Madrid, ESP
FORSLUND Lennart, Uppsala, SWE
REGNSTROEM Jan, London, GBR

FDA

PARKS Mary, Rockville, USA
STOCKBRIDGE Norman, Rockville, USA
UNGER Ellis, Rockville, USA

INDUSTRY

ANDRE Stéphane, F. Hoffmann-La Roche, CHE
ARENS Hans-Juergen, Fresenius, GER
BERKOWITZ Scott, Bayer, USA
BURTON Paul, J&J, USA
BUYSSE Jerry , Relypsa, USA
COOK-BRUNS Nancy, Bayer, GER
DELIARGYRIS Efthymios, MedCo, GER
FERGUSON Terry J, AstraZeneca, USA
HIRSHBERG Boaz, AstraZeneca, USA
HISLOP Colin, Anthera Pharma, USA
HORROW Jay, AstraZeneca, USA
KALLEND David, F. Hoffmann-La-Roche, CHE
KHDER Yasser, Boehringer Ingelheim, FRA
KOGLIN Joerg, Merck, USA
KUPFER Stuart, Takeda, USA
MENDELSOHN Michael, Merck, USA
MISSELWITZ Franck, Bayer, GER
MUNTENDAM Pieter, BG Medicine, USA
PEREZ Alfonso, Takeda, USA
ROESSIG Lothar, Bayer, GER
SZAFIR Deborah, F. Hoffmann-La Roche, CHE
TURGONYI Eva, Pfizer, GBR
ZALEWSKI Andrew, Novartis, USA

GENERAL PRESENTATION

Organized in collaboration with the European Society of Cardiology Working Group on Cardiovascular Pharmacology and Drug Therapy, CVCT Forum is a meeting specifically and totally dedicated to the discussion of clinical trials in cardiovascular disease.

CVCT Forum is attended by experts principally engaged in cardiovascular clinical trials (hence it's name). Participants are among the group of major international opinion leaders and come from various functions linked with primary care, pharmaceutical industry, pharmaceutical regulatory bodies, and publishing houses from around the world (US, Canada, Asia and Europe).

The outstanding faculty members are committed to disseminating concise data from controlled clinical trials that contribute to better clinical care and to discussing and identifying issues and relevant information. Such as how to do better clinical trials, how to satisfy regulatory authorities, and most importantly, how to improve cardiovascular health care.

The CVCT meetings are 'grass root' meetings, attended by individuals who are eager to communicate with one another and to share experiences with primary care physicians and the people that create and analyze major trials. CVCT meetings are primarily oriented toward discussion among persons as opposed to lecturing to a broad audience. Thought process counts, communication (during the meeting, but more importantly informal discussions outside of the meeting) is the important agenda, as opposed to dictating doctrine.

The format of the meeting is set to fulfill these aims. Beyond plenary sessions the meeting is structured with a variety of small interactive brainstorming workshops, expert discussions, how-to-sessions and consensus building workshops.

The discussion takes place with a selected audience of opinion leaders, clinical trialists, pharmaceutical industry partners, regulators, investigators and cardiologists.

CVCT Forum aims to:

- Familiarize practitioners and young investigators with the science of clinical trials from trial protocol design to trial result interpretation
- Examine the background of knowledge which led to the design of major trials
- Identify and understand best evidence from clinical trials
- Examine the consequences of trial results on the updating of guidelines
- Consider the consequences and relative weight of Evidence based vs Mechanism based and Marketing based medicine
- Identify emerging important issues in cardiovascular medicine
- Examine opportunities and needs for new trials

We do hope that you will share with us the excitement of this unique learning experience and we are very happy to welcoming you to Paris.

Pr. Faiez ZANNAD *Pr. Bertram PITT* *Pr. Christopher O'CONNOR*

SUMMARY

SCIENTIFIC PROGRAM

ACCREDITATION

EBAC

European Board for Accreditation in Cardiology

The CVCT Forum is accredited by the European Board for Accreditation in Cardiology (EBAC) for 12 hours of External CME credits. Each participant should claim only those hours of credit that have actually been spent in the educational activity. EBAC works according to the quality standards of the European Accreditation Council for Continuing Medical Education (EACCME), which is an institution of the European Union of Medical Specialists (UEMS).

Duke School of Medicine

The Duke University School of Medicine designates this educational activity for a maximum of 14 AMA PRA Category 1 Credits TM.

Physicians should only claim credit commensurate with the extent of their participation in the activity.

Global CVCT Forum supports **Young Investigators** through a grant scheme enabling them to access and participate to CVCT Forum, an event dedicated to clinical trials in cardiovascular disease, with the aim of making them learn from and network with key decision makers, principal investigators, sponsors, and regulatory experts, and shape their future practice toward CV clinical trial related activities.

The Grant includes one full scientific registration to attend CVCT 2011 in Paris as well as hotel accommodation and a travel grant.

FRIDAY 2 DECEMBER 2011

	09.00 - 10.30	10.30 - 11.00 • Coffee break	11.00 - 13.30	13.30 - 14.00 • Coffee break	14.00 - 16.00	16.00 - 16.30 • Coffee break	16.30 - 18.00
BACCARAT	**WORKSHOP** Atherosclerosis and lipid lowering trialists workshop		**WORKSHOP** Atherosclerosis and lipid lowering trialists workshop *Lunch served during the session*		**PLENARY SESSION** Heart rate: a biomarker and a biotarget in cardiovascular disease		**PLENARY SESSION** Expert statisticians and trialists discuss the major trials of the year
BOLERO	**WORKSHOP** RAAS trialists workshop		**WORKSHOP** RAAS trialists workshop *Lunch served during the session*		**PLENARY SESSION** Geographical variation in clinical outcomes in cardiovascular drug trials: fact or artefact? Joint session CVCT, ESC Working Group on Cardiovascular Pharmacology and Drug Therapy International Society of Cardiovascular Pharmacology		

SATURDAY 3 DECEMBER 2011

	08.30 - 10.30	10.30 - 11.00 • Coffee break	11.00 - 12.00	12.00 - 13.30	13.30 - 14.00 • Coffee break	14.00 - 15.25	15.25 - 15.45 • Coffee break	15.45 - 18.00
BACCARAT	**WORKSHOP** Expert opinion consensus workshop: The use of mineralocorticoid receptor antagonist, MRA in clinical practice		**WORKSHOP** Expert opinion consensus workshop: The use of mineralocorticoid receptor antagonist, MRA in clinical practice	**MEET & EAT** **With the Experts:** Serum potassium in cardiorenal trials *Lunch served during the session*		**WORKWSHOP** Thrombosis trialists expert workshop		**WORKWSHOP** Thrombosis trialists expert workshop
BOLERO	**WORKSHOP** Diabetes trialists workshop		**WORKSHOP** Diabetes trialists workshop	**MEET & EAT** **With the Experts:** Is Heart Failure a thrombotic disease? Time for a trial? *Lunch served during the session*		**WORKSHOP** Cardiovascular personalized medicine trialists workshop: Guiding therapy with biomarkers and telemonitoring		**WORKSHOP** Cardiovascular personalized medicine trialists workshop: Guiding therapy with biomarkers and telemonitoring

09.00 - 13.30 BACCARAT ROOM — Workshop Session

ATHEROSCLEROSIS AND LIPID LOWERING TRIALISTS WORKSHOP

Chairpersons: John CHAPMAN, Paris, FRA - Wolfgang KOENIG, Ulm, GER
Webex co-chairperson: Giuseppe ROSANO, Rome, IT

The territories of statin therapy are being extended to patients with "normal" LDL-C, based on risk scoring and CRP levels. This creates new implementation challenges. Even after LDL-C is aggressively controlled to very low levels with statin therapy, low HDL-C still remains a significant cardiovascular risk factor.

Low serum levels of HDL-C or of apolipoprotein A-1, (ApoA-1), the major protein of HDL particles, are consistently associated with increased risk for all forms of atherosclerotic disease.

Lipoprotein-associated phospholipase A2, (LpPLA2) is part of a family of lipases involved in the modification of lipids within the atheroma and may be a complimentary therapeutic target to the reduction of LDL-C.

There is great interest in developing a reliable measure of atherosclerotic disease activity that can serve as an index of response to anti-atherosclerotic therapies.

Topics for discussion:

Atherosclerosis drugs on the horizon

- Newer CETP inhibitors
  Bart STAELS, Lille, FRA
- Apolipoprotein mimetics
  John CHAPMAN, Paris, FRA
- Apolipoprotein upregulators
  Robert ROSENSON, New York, USA

How to target the right population?

- Scoring systems and risk-guided therapy
  Speaker: François GUEYFFIER, Lyon, FRA
  Discussant: David WOOD, London, GBR
- Biomarkers and bio-imaging. Where they may help best?
  Speakers: - Imaging atherosclerosis Ahmed TAWAKOL, New York, USA
  - Is CRP an independent risk predictor in patients receiving statins? Peter SEVER, London, GBR
  Discussant: Wolfgang KOENIG, Ulm, GER

Addressing the regulatory challenges

Speaker: Lennart FORSLUND, Uppsala, SWE
Discussants: David KALLEND, F. Hoffmann-La-Roche, CHE - Mary PARKS, Rockville, USA

Can PMS and conditional approval help?

Speaker: Gonzalo CALVO, Madrid, ESP
Discussants: Angeles ALONSO, Madrid, ESP - Norman STOCKBRIDGE, FDA, Rockville, USA

Drugs: Statins - Anacetrapib - Dalcetrapib - Darapladib - Evacetrapib - Rilapladib - Niacin - Rosuvastatin Varespladib

Trials: AIM-HIGH - DAL OUTCOMES - DEFINE - SOLID TIMI - STABILITY - VISTA-16

Expert Panellists:

ANDRE Stéphane, F. Hoffmann-La Roche, CHE - ALONSO Angeles, Madrid, ESP – ATAR Dan, Oslo, NOR
CALVO Gonzalo, Madrid, ESP - CHAPMAN John, Paris, FRA - FORSLUND Lennart, Uppsala, SWE
GOEHRS Jean Marie, Versailles, FRA - GORDON David, Bethesda, USA - GUEYFFIER François, Lyon, FRA
HISLOP Colin, Anthera Pharmaceuticals, USA - HORROW Jay, Astra Zeneca, USA
KALLEND David, F. Hoffmann-La-Roche, CHE - KOENIG Wolfgang, Ulm, GER - LAUER Michael S, Bethesda, USA
LEWIS Basil, Haïfa, ISR - MENDELSOHN Michael, Merck, USA - PARKS Mary, Rockeville, USA
PLUTZKY Jorge, Boston, USA - POPOV Vladimir, Moscow, RUS - ROSANO Giuseppe, Roma, ITA
ROSENBERG Yves, Bethesda, USA - ROSENSON Robert, New York, USA
SEVER Peter, London, GBR - STAELS Bart, Lille, FRA - STOCKBRIDGE Norman, Rockville, USA
SZAFIR Deborah, F. Hoffmann-La Roche, CHE - TEDGUI Alain, Paris, FRA - TOUBOUL Pierre Jean, Paris, FRA
TAWAKOL Ahmed, New York, USA - WOOD David, London, GBR

09.00 - 13.30 BOLERO ROOM — Workshop Session

THE RAAS TRIALISTS WORKSHOP

Chairpersons: Georges BAKRIS, Chicago, USA - Bernard WAEBER, Lausanne, CHE

The use of drugs aimed at inhibiting the RAAS is one of the most remarkable advances in CV medicine. Combining an ACE-Inhibitor and an Angiotensin receptor blocker did not lead to a significant benefit in patients with high risk, nor in patients with acute myocardial infarction, although some benefit is achieved with this combination in patients with chronic heart failure. Combining a mineralocorticoid receptor antagonist, (MRA) to ACE-Inhibitor or an Angiotensin receptor blocker was proven to be a much better option in heart failure. Various ways to maximize the benefit of agents targeting the RAAS are being explored. These include

- Trials with new drug entities:
  - Direct renin inhibitors
  - Agents with super ARB activity
  - New MRA and aldosterone synthase inhibitors
  - Hybrid ARB and NEP inhibitors
- Better tackling of renal and potassium safety issues
- Exploring new indications for old drugs

With generic spironolactone available and being the default option, the challenge with new aldosterone antagonists is differentiation. Head-to-head comparisons being not on the agenda, creative thinking is needed to explore new indications in new patient populations.

Topics for discussion:

New Renin Angiotensin Aldosterone System antagonists on the horizon — John MCMURRAY, Glasgow, GBR

The need for new types of morbidity-mortality trials in hypertension — Bernard WAEBER, Lausanne, CHE

Development challenges

- Pharmacological differentiation in hypertension
  Speaker: Bernard WAEBER, Lausanne, CHE
  Discussants: Georges BAKRIS, Chicago, USA - Stuart KUPFER, Takeda, USA
- Pharmacological differentiation in Heart Failure
  Speaker: Faiez ZANNAD, Nancy, FRA
  Discussants: Mihai GHEORGHIADE, Chicago, USA - Bertram PITT, Ann Arbor, USA

New indications
Speaker: Domenic SICA, Richmond, USA
Discussant: Frank MISSELWITZ, Bayer, GER - Luis RUILOPE, Madrid, ESP

Optimization of RAAS inhibition: Uptitration vs. Combination vs. Guided-therapy? Limits and alternatives
Speaker: Marc PFEFFER, Boston, USA
Discussant: Aldo Pietro MAGGIONI, Florence, ITA

Approvability of new RAAS
Speaker: Karl SWEDBERG, Gothenburg, SWE
Discussants: Joerg KOGLIN, Merck, USA - Ileana L PIÑA, New York, USA

Drugs: Aliskiren - Azilsartan - BAY 94-8862 - eplerenone - LCI699 - LCZ 696 - Olmesartan

Trials: ART - ACCELERATE - AQUARIUS - ALBATROSS - APOLLO - ASTRONAUT - ATMOSPHERE - PEARL-HF PARADIGM - REMINDER - ROADMAP - TOPCAT

Expert Panellists:

ADAMS Kirkwood, Chapel Hill, USA - ARENS Hans-Juergen, Fresenius, GER - BAKRIS Georges, Chicago, USA
BRISTOW Michael, Broomfield, USA - BUYSSE Jerry, Relypsa, USA - COHEN SOLAL Alain, Paris, FRA
FELKER Michael, Durham, USA - GHEORGHIADE Mihai, Chicago, USA - GRIMM Richard, Minneapolis, USA
KJELDSEN Keld, Copenhagen, DEN - KOGLIN Joerg, Merck, USA - KUPFER Stuart, Takeda, USA
MAGGIONI Aldo Pietro, Florence, ITA - MCDONALD Kenneth, Dublin, IRE - MCMURRAY John, Glasgow, GBR
MASCETTE Alice, Bethesda, USA - MASSY Ziad, Amiens, FRA - MISSELWITZ Franck, Bayer, GER O'CONNOR Christopher, Durham, USA - PATHAK Atul, Toulouse, FRA - PEREZ Alfonso, Takeda, USA
PFEFFER Marc, Boston, USA - PIÑA Ileana L., New york, USA - PITT Bertram, Ann Arbor, USA
ROESSIG Lothar, Bayer, GER - ROQUES Bernard P., Paris, FRA - ROSANO Giuseppe, Roma, ITA
ROSENBERG Yves, Bethesda, USA - RUILOPE Luis, Madrid, ESP - SABBAH Hani, Detroit, USA
SWEDBERG Karl, Gothenburg, SWE - TAVAZZI Luigi, Cotignola, ITA - TURGONYI Eva, Pfizer, GBR
WAEBER Bernard, Lausanne, CHE - ZALEWSKI Andrew, Novartis, USA - ZANNAD Faiez, Nancy, FRA

FRIDAY 2 DECEMBER 2011

14.00 - 16.00 BACCARAT ROOM — Plenary Session

HEART RATE: A BIOMARKER AND A BIOTARGET IN CARDIOVASCULAR DISEASE

Chairpersons: Jeffrey S. BORER, New York, USA - Faiez ZANNAD, Nancy, FRA

Webex co-chairpersons: Daniela DOBRE, Nancy, FRA - Kurt STOSCHITZKY, Graz, AUT

Heart rate: a biomarker and a biotarget in health and disease – insight from epidemiology and pathophysiology
Kim FOX, London, GBR

Slowing heart rate in coronary artery disease and in heart failure – the distinct roles of different heart rate-lowering agents
Jeffrey S. BORER, New York, USA

Evidence from recent trials with ivabradine – updating the guidelines and clinical significance
Karl SWEDBERG, Gothenburg, SWE

Debate: Guidelines and implementation challenges in clinical practice

Expert Panellists:

ADAMS Kirkwood, Chapel Hill, USA - BERDEAUX Alain, Créteil, FRA - BORER Jeffrey, New York, USA
BRISTOW Michael, Broomfield, USA - CLELAND John, Hull, GBR - COHEN SOLAL Alain, Paris, FRA
DARGIE Henry, Glasgow, GBR - FELKER Michael, Durham, USA - FOX Kim, London, GBR
GHEORGHIADE Mihai, Chicago, USA - GUEYFFIER François, Lyon, FRA - JOUVEN Xavier, Paris, FRA
LAUER Michael S, Bethesda, USA - MCMURRAY John, Glasgow, GBR - MAGGIONI Aldo Pietro, Florence, ITA
MCDONALD Kenneth, Dublin, IRE - O'CONNOR Christopher, Durham, USA - PATHAK Atul, Toulouse, FRA
PFEFFER Marc, Boston, USA - SWEDBERG Karl, Gothenburg, SWE - PITT Bertram, Ann Arbor, USA
PIÑA Ileana L., New York, USA - ROSANO Giuseppe, Roma, ITA - SABBAH Hani, Detroit, USA
STOSCHITZKY Kurt, Graz, AUT- TAVAZZI Luigi, Cotignola, ITA - ZANNAD Faiez, Nancy, FRA

14.00 - 16.00 BOLERO ROOM — Plenary Session

GEOGRAPHICAL VARIATION IN CLINICAL OUTCOMES IN CARDIOVASCULAR DRUG TRIALS: FACT OR ARTEFACT?

Joint session : CVCT, ESC Working Group on Cardiovascular Pharmacology and Drug Therapy
International Society of Cardiovascular Pharmacology

Chairpersons: Juan Carlos KASKI, President, ISCP, London, GBR and Angeles ALONSO, ESC Working Group on Cardiovascular Pharmacology and Drug Therapy, Madrid, ESP

Hypertension trials
Luis RUILOPE, Madrid, ESP

Heart Failure trials
Felipe MARTINEZ, Cordoba, ARG

Atrial fibrillation trials
Gheorge Andrei DAN, Bucharest, ROM

ACS trials
Sidney GOLDSTEIN, Ann Arbor, USA

16.30 - 18.00 BACCARAT ROOM — Plenary Session

EXPERT STATISTICIANS AND TRIALISTS DISCUSS THE MAJOR TRIALS OF THE YEAR

Chairpersons: John MCMURRAY, Glasgow, GBR - Faiez ZANNAD, Nancy, FRA

Webex co-chairpersons: François GUEYFFIER, Lyon, FRA - Angeles ALONSO, Madrid, ESP

Medicine deals with treatments that work often but not always, so treatment success must be based on probability. This unique session is meant to be educational and possibly controversial. Interpreting trial results requires a good understanding of statistics and trial methodology. Senior statisticians and clinical trialists debate their own views as well as tips and tricks for understanding the most recent trials of the year.

Speaker: Stuart POCOCK, London, GBR
Discussant: Marc PFEFFER, Boston, USA

Expert Panellists: All CVCT faculty members

08.30 - 12.00 BOLERO ROOM Workshop Session

DIABETES TRIALISTS WORKSHOP

Chairpersons: Sverre E KJELDSEN, Olso, NOR - Richard GRIMM, Minneapolis, USA

While a number of new drugs with new pharmacological mechanisms for glucose control have recently emerged, long-term benefits and harms of diabetes medications remain unclear.

The value of the surrogate glycaemia control and HbA1 C, the usual endpoint on which approval of diabetes drugs is based is being strongly challenged.

The debate on whether newer, (and older) oral hypoglycaemic drugs may cause deleterious CV effects has been fuelled by the results of recent trials and controversial meta-analyses.

Contrasting and balancing the accepted benefits of glucose control and micro-vascular prevention vs. the potential risks and less proven benefits of macro vascular complications has led the FDA to issue a risk evaluation and mitigation strategy (REMS) as well as proscriptive industry guidelines requesting the evaluation of CV risk in all new anti-diabetic therapies.

Implementing the FDA new type of adaptive design non-inferiority trials is challenging.

Topics for discussion:

Are the cardiovascular risks related to new anti-diabetes agents drug specific/class specific?
Speaker: Jorge PLUTZKY, Boston, USA
Discussants: John CLELAND, Hull, GBR - Richard GRIMM, Minneapolis, USA

Micro vs. macrovascular disease progression endpoints
Speaker: Peter SLEIGHT, Oxford, GBR
Discussants: Gilles DAGENAIS Quebec, CAN - David G. WARNOCK, Birmingham, USA

Are the current megatrials addressing the unmet needs?
Speaker: Stuart POCOCK, London, GBR
Discussant: David GORDON, Bethesda, USA

Time for comparative effectiveness trials?
Speaker: Yves ROSENBERG, NHLBI, Bethesda, USA
Discussant: Gonzalo CALVO, Madrid, ESP

Methodological, steering, ethical and economic challenges of the new FDA industry guidelines
Speaker: Guntram SCHERNTHANER, Vienna, AU
Discussant: Boaz HIRSHBERG, AstraZeneca, USA

Drugs: Albiglutide - Aleglitazar - Alogliptin - Exenitide - Canagliflozin - Glimeperide - Liraglutide - Lixisenatide Pioglitazone - Rosiglitazone - Saxagliptin - Sitagliptin - Vildagliptin

Trials: ALECARDIO - CANVAS - CAROLINA - ELIXA - EXAMINE - EXSCEL - LEADER - SAVOR - TECOS

Expert Panellists:

ADAMS Kirkwood, Chapel Hill, USA - CALVO Gonzalo, Madrid, ESP - CLELAND John, Hull, GBR
DAGENAIS Gilles Quebec, CAN - DOMANSKI Michael, New York, USA - FORSLUND Lennart, Uppsala, SWE
GUEYFFIER François, Lyon, FRA - GORDON David, Bethesda, USA - HIRSHBERG Boaz, Astrazeneca, USA
KHDER Yasser, Boehringer Ingelheim, FRA - KJELDSEN Sverre E, Olso, NOR- KUPFER Stuart, Takeda, USA
KOENIG Wolfgang, Ulm, GER - PLUTZKY Jorge, Boston, USA - POCOCK Stuart, London, GBR
ROSANO Giuseppe, Roma, ITA - ROSENBERG Yves, Bethesda, USA - SCHERNTHANER Guntram, Vienna, AUT
SICA Domenic, Farmington, USA - SLEIGHT Peter, Oxford, GBR - STAELS Bart, Lille, FRA
SWYNGHEDAUW Bernard, Paris FRA - WARNOCK David G., Birmingham, USA - WOOD David, London, GBR

SATURDAY 3 DECEMBER 2011

08.30 - 12.00 BACCARAT ROOM — Workshop Session

EXPERT OPINION CONSENSUS WORKSHOP
THE USE OF MINERALOCORTICOID RECEPTOR ANTAGONIST, MRA IN CLINICAL PRACTICE

Chairpersons: Luigi TAVAZZI, Cotignola, ITA - Adrian VOORS, Groningen, NDL

Webex co-chairpersons: Luca BETTARI, Brescia, ITA - Atul PATHAK, Toulouse, FRA

Recent high level evidence from trials with eplerenone, (EPHESUS and EMPHASIS), consistent with the results of the earlier spironolactone RALES trial is likely to establish MRAs as third drugs in addition to ACE inhibitors, (or ARBs) and beta-blockers across the complete spectrum of severity of chronic heart failure patients with left ventricular systolic dysfunction. Beyond the expected revision in the international guidelines, it is important that more extensive and specific practical guidance is provided to clinicians about the practical use of MRAs. This session is to deliver an Expert Consensus Statement paper that may complement current international guidelines.

Ideal current indications
Speaker: Bertram PITT, Ann Arbor, USA
Discussant: Alain COHEN SOLAL, Paris, FRA

Spironolactone or Eplerenone? Class effect, differential effects
Speaker: Alan STRUTHERS, Dundee, GBR
Discussant: Aldo MAGGIONI, Florence, ITA

Dosing: Dose-related benefit and risk issues
Speaker: Adrian VOORS, Groningen, NDL
Discussant: Luis RUILOPE, Madrid, ESP

Understanding, predicting, preventing and managing renal and potassium safety issues
Speaker: Patrick ROSSIGNOL, Nancy, FRA
Discussant: Georges BAKRIS, Chicago, USA

Targeting the right patient: Mechanistic insights
Speaker: Faiez ZANNAD, Nancy, FRA
Discussant: Johannes BAUERSACHS, Hanover, GER

Guidelines: Overview of the current international guidelines and Implementation issues
Speaker: John MCMURRAY, Glasgow, GBR
Discussant: Christopher O'CONNOR, Durham, USA

Expert Panellists:

ARENS Hans-Juergen, Fresenius, GER - ALONSO Angeles, EMEA, Madrid, ESP - BAKRIS Georges, Chicago, USA
BAUERSACHS Johannes, Hanover, GER - BRISTOW Michael, Broomfield, USA - COHEN SOLAL Alain, Paris, FRA
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GHEORGHIADE Mihai, Chicago, USA - ISNARD Richard, Paris, FRA - MAGGIONI Aldo Pietro, Florence, ITA
MASSY Ziad, Amiens, FRA - MCMURRAY John, Glasgow, GBR - MENDELSOHN Michael, Merck, USA
MISSELWITZ Frank, Bayer, GER - O'CONNOR Christopher, Durham, USA - PATHAK Atul, Toulouse, FRA
PFEFFER Marc, Boston, USA - PITT Bertram, Ann Arbor, USA - PIÑA Ileana, Cleveland, USA
ROSSIGNOL Patrick, Nancy, FRA - RUILOPE Luis Miguel, Madrid, ESP - SABBAH Hani, Detroit, USA
SICA Domenic, Richmond, USA - STRUTHERS Alan, Dundee, GBR - SWEDBERG Karl, Gothenburg, SWE
TAVAZZI Luigi, Cotignola, ITA - VOORS Adrian, Groningen, NDL - ZANNAD Faiez, Nancy, FRA

12.00 - 13.30 BACCARAT ROOM — Plenary Session

SERUM POTASSIUM IN CARDIORENAL TRIALS

Chairpersons: Ziad MASSY, Amiens, FRA - Bertram PITT Ann Arbor, USA

Webex co-chairpersons: Keld KJELDSEN, Copenhague, DEN - Patrick ROSSIGNOL, Nancy, FRA

The pathophysiology of serum potassium in cardiorenal disease George BAKRIS, Chicago, USA
Serum potassium and cardio(renal) outcomes in cardiovascular clinical trials of RAAS therapy Bertram PITT, Ann Arbor, USA
Hyperkalemia: Physiology, Control and Potassium Binder Mechanism of Action Jerry BUYSSE, Relypsa, USA

Expert Panellists:

ARENS Hans-Juergen, Fresenius, GER - BAKRIS George, Chicago, USA - BAUERSACHS Johannes, Hanover, GER
BUYSSE Jerry, Relypsa, USA - CLELAND John, Hull, GBR - DARGIE Henry, Glasgow, GBR - FELKER Michael, Durham, USA
KJELDSEN Keld, Copenhagen, DEN - LAVILLE Maurice, Lyon, FRA - MASSY Ziad, Amiens, FRA
MISSELWITZ Frank, Bayer, GER - PITT Bertram, Ann Arbor, USA - ROSANO Giuseppe, Rome, ITA
ROSSIGNOL Patrick, Nancy, FRA - SICA Domenic, Richmond, USA - WARNOCK David G., Birmingham, USA

12.00 - 13.30 BOLERO ROOM Meet and Eat with the Experts

IS HEART FAILURE A THROMBOTIC DISEASE? TIME FOR A TRIAL?

Chairpersons: Mihai GHEORGHIADE, Chicago, USA - Faiez ZANNAD, Nancy, FRA

In spite of major progress in the management of chronic heart failure, the post discharge event rate (hospitalization and mortality) in patients admitted with heart failure is around 35 to 50% at six months. Sudden death is the mode of death in 30% of patients and is frequently due to new coronary (thrombotic) occlusion and not only to lethal arrhythmias.

There is increasing evidence that heart failure is associated with a hypercoagulable state, platelet activation and endothelial dysfunction. It is possible that thromboembolic events contribute to the high mortality and re-hospitalization rate in this patient population.

Decompensated heart failure is a recognized risk factor for venous thromboembolism.
The role of antithrombotic therapy in patients with heart failure is still unclear and data, coming mostly from poorly designed studies were restricted to patients with chronic stable (not acute) heart failure.

The conclusions drawn from post hoc analyses do not support definitive beneficial effect for antithrombotic therapy in heart failure. A safe and effective "Antithrombotic agent" may help indirectly to understand how much thrombotic events contribute to the high post discharge event rate in acute heart failure.

On another hand, thrombin and factor Xa act on specific protease-activated receptors (PARs), which are present on cardiomyocytes and are involved in vascular development and a variety of other biological processes including apoptosis and remodeling.

In most ACS trials, patients with low EF tend to benefit most from anti-thrombotic therapy.

Further trials are needed, especially concerning the effect of thrombin inhibitors and other anticoagulant drugs on cardiomyocyte function and cardiac remodeling in acute coronary syndromes.

Thromboembolism and antithrombotic therapy in patients with heart failure in sinus rhythm
Current Status and Future Directions
Christopher O'CONNOR, Durham, USA

Thrombin inhibition in the ischemic and failing myocardium. Pleiotropic protection beyond anticoagulation?
Efthymios DELIARGYRIS, MedCo, GER

New trial opportunities with the new anti-thrombotic agents in heart failure syndromes.
Faiez ZANNAD, Nancy, FRA

Debate: Time for a new trial?

Expert Panellists:

AGEWALL Stefan, Oslo, NOR - ALONSO Angeles, EMEA, Madrid, ESP - BERKOWITZ Scott, Bayer, USA
BEYGUI Farzin, Paris, FRA - BONNEFOY Eric, Lyon, FRA - BORER Jeffrey, New York, USA
BURTON Paul, J&J, USA - CALVO Gonzalo, Madrid, ESP - COHEN SOLAL Alain, Paris, FRA
COOK-BRUNS Nancy, Bayer, GER - DELIARGYRIS Efthymios, MedCo, GER - FILIPPATOS Gerasimos, Athens, GRE
FORSLUND Lennart, Uppsala, SWE - GHEORGHIADE Mihai, Chicago, USA - GOLDSTEIN Sidney, Ann Arbor, USA ISNARD Richard, Paris, FRA - KHDER Yasser, Boehringer Ingelheim, FRA - KOGLIN Joerg, Merck, USA
LEWIS Basil, Haïfa, ISR - MAGGIONI Aldo Pietro, Florence, ITA - O'CONNOR Christopher, Durham, USA
PFEFFER Marc, Boston, USA - ROSENBERG Yves, Bethesda, USA - ROSSIGNOL Patrick, Nancy, FRA
SIMON Tabassome, Paris, FRA - STOCKBRIDGE Norman, Rockville, USA
SWEDBERG Karl, Gothenburg, SWE - UNGER Ellis, Rockville, USA - VERHEUGT Freek, Amsterdam, NDL
ZANNAD Faiez, Nancy, FRA

14.00 - 18.00 BACCARAT ROOM — Workshop Session

THROMBOSIS TRIALISTS EXPERT WORKSHOP

Chairpersons: Sidney GOLDSTEIN, Ann Arbor, USA - Freek VERHEUGT, Amsterdam, NDL

Webex co-chairpersons: Stefan AGEWALL, Oslo, NOR - Basil LEWIS, Haïfa, ISR

A host of novel oral anticoagulants nearing or already on the market, aim at replacing warfarin for a variety of indications, including prevention and treatment of VTE and prophylaxis of stroke in patients with AF.

Three of the new anticoagulants, the factor Xa inhibitor, rivaroxaban and apixaban and the direct thrombin inhibitor dabigatran, (Pradaxa, Boehringer Ingelheim), are available for VTE prevention and dabigatran has also recently been approved for stroke prevention in atrial fibrillation.

Some agents are also in trials for acute coronary syndrome, but development here is more challenging because of the declining event rate and the question arises if the risk is so low, can you gain anything more by adding more effective antithrombotic therapy?

There is no clear relationship between anticoagulant or anti-platelet activity and clinical endpoint event rates. Therefore, the single dose that is taken into phase III studies provides inadequate evidence of the optimal use of the drug. The FDA preferred approach is to take multiple doses into phase III and avoid over-valuing bleeding. Different definitions of bleeding across trials and variations in the way that bleeding data are captured make comparisons between studies difficult. Harmonization of collection and reporting of bleeding data in trials of antithrombotic drugs would be welcomed. Balancing risk and benefit is essential and new endpoints for predicting and assessing the bleeding risk may help in comparative studies.

Combining safety and efficacy endpoints can make interpretation of study outcomes problematic. 'Net clinical benefit' is not a substitute for benefit-risk. Time has an effect. One component can drive the results. Using more endpoints is not always better and results vary depending on the combination of endpoints.

Topics for discussion:

Defining/approving the "right" dose. The FDA – Trialists dilemma
Speaker: Jeffrey BORER, New York, USA
Discussants: Yasser KHDER, Boehringer Ingelheim, FRA - Ellis UNGER, FDA, Rockville, USA

Endpoints combining benefit and bleeding risk
Speaker: Roxana MEHRAN, New York, USA
Discussant: Paul BURTON, J&J, USA

Regional differences and globalization issues
Speaker: Sidney GOLDSTEIN, Ann Arbor, USA
Discussant: Efthymios DELIARGYRIS, MedCo, GER

Atrial fibrillation: Unmet needs. Targeting gaps with warfarin therapy
Speaker: John MCMURRAY, Glasgow, GBR

ACS: add-on and antithrombotic background therapy issues
Speaker: Eric BONNEFOY, Lyon, FRA
Discussants: Freek W.A VERHEUGT, Amsterdam, NDL - Scott BERKOWITZ, Bayer, USA

Drugs: Apixaban - atopaxar - Betrixiban, Bivaluridin - Cangrelor - Cilostazol - Dabigatran - Edoxaban - Elinogrel Fondaparinux - Prasugrel - Rivaroxaban - Ticagrelor - Tecarfarin - Varopaxar

Trials:

Atrial Fibrillation: ARISTOTLE - AVERROES, BOREALIS - CHAMPION - Engage AF TIMI48 - EMBRACE AC PEGASUS - RELY - RELY-ABLE - ROCKET AF

Acute Coronary Syndromes: ACCOAST - ATLAS ACS 2-TIMI 51 - CHAMPION - CHAMPION-PHENIX CHAMPION PLATFORM - EUROMAX - LANCELOT-CAD - RIVAROXACS - TRACER ACS - TRAP2P - TRANSLATE ACS

Expert Panellists:

AGEWALL Stefan, Oslo, NOR - BERKOWITZ Scott, Bayer, USA - BONNEFOY Eric, Lyon, FRA
BORER Jeffrey, New York, USA - BURTON Paul, J&J, USA - CALVO Gonzalo, Madrid, ESP - CLELAND John, Hull, GBR
COOK-BRUNS Nancy, Bayer, GER - DELIARGYRIS Efthymios, MedCo, GER - FERGUSON Terry J, Astra Zeneca, USA
FORSLUND Lennart, Uppsala, SWE - GOLDSTEIN Sidney, Ann Arbor, USA - KHDER Yasser, Boehringer Ingelheim, FRA
LEWIS Basil, Haïfa, ISR - MEHRAN Roxana, New York, USA - MISSELWITZ Frank, Bayer, GER
POPOV Vladimir, Moscow, RUS - ROSENBERG Yves, NHLBI, Bethesda, USA - SIMON Tabassome, Paris, FRA
UNGER Ellis, FDA, Rockville, USA - VERHEUGT Freek, Amsterdam, NDL

14.00 - 18.00 BOLERO ROOM Workshop Session

CARDIOVASCULAR PERSONALIZED MEDICINE TRIALISTS WORKSHOP GUIDING THERAPY WITH BIOMARKERS AND TELEMONITORING

Chairpersons: Alexandre MEBAZAA, Paris, FRA - Christopher O'CONNOR, Durham, USA

The search for biomarkers that can forecast risk is one of the most active research areas in cardiology.

This has turned up a few promising novel biomarkers. Although the validation process of a new biomarker is now well established, establishing the clinical usefulness of biomarkers is still challenging.

Risk guided therapy trials and biomarker monitored therapy optimization are fast growing areas of investigation.

Introduction: are oncologists doing a better job than cardiologists using biomarkers?
Ludwig NEYSES, Manchester, GBR

Topics for discussion:

Risk models and their relevance to therapeutic decision-making
Speaker: François GUEYFFIER, Lyon, FRA
Discussant: Nancy GELLER, Bethesda, USA

Validation of a therapeutic decision making tools

For selecting/initiating, indicating a therapy
Speaker: Michael BRISTOW, Broomfield, USA
Discussant: Pieter MUNTENDAM, BG Medicine, USA

For optimizing therapy
Speaker: Kirkwood ADAMS, Chapel Hill, USA
Discussant: Adrian VOORS, Groningen, NDL

Biomarker approach to the early identification of events
Michael FELKER, Durham, USA

The prerequisites for a useful signal
Ileana L PIÑA., New York, USA

Approvability of a biomarker guided therapy
Speaker: Norman STOCKBRIDGE, Rockville, USA

Public funding of cardiovascular personalized medicine research

The EU Framework Programme: Virginija DAMBRAUSKAITE, Brussels, BEL
The NHLBI Perspective: Alice MASCETTE, Bethesda, USA

Drugs/biomarkers: beta-1 receptor genotype, Bucindolol - Copeptin, Tolvaptan - Ferritin, Ferric Carboxymaltose Galectin-3, Aldosterone Antagonists - CRP, Rosuvastatin - MIBG - Procalcitonin - sTREM1

Trials: ACTIVATE - ADREVIEW - ARCA - CHAMPION - FAIR-HF - HOME-BNP - JUPITER

Expert Panellists:

ADAMS Kirkwood, Chapel Hill, USA - ALONSO Angeles, EMEA, Madrid, ESP - BRISTOW Michael, Broomfield, USA
DAMBRAUSKAITE Virginija, Brussels, BEL - DARGIE Henry, Glasgow, GBR - FELKER Michael, Durham, USA
FILIPPATOS Gerasimos, Athens, GRE - FIUZAT Mona, Durham, USA - GELLER Nancy, Bethesda, USA
GORDON David, NHLBI, Bethesda, USA - GUEYFFIER François, Lyon, FRA - ISNARD Richard, Paris, FRA
REGNSTROEM Jan, EMEA, London, GBR - MEBAZAA Alexandre, Paris, FRA - MASCETTE Alice, Bethesda, USA
MUNTENDAM Pieter, BG Medicine, USA - NEYSES Ludwig, Manchester, GBR
O'CONNOR Christopher, Durham, USA - PATHAK Atul, Toulouse, FRA - PIÑA Ileana L., New York, USA
POCOCK Stuart, London, GBR - STOCKBRIDGE, Norman, Rockeville, USA - VOORS Adrian, Groningen, NDL
ZALEWSKI Andrew, Novartis, USA - ZANNAD Faiez, Nancy, FRA

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Stephanie Prate

BG MEDICINE

BG Medicine, Inc. is a life sciences company focused on the discovery, development, and commercialization of novel diagnostics to improve patient outcomes and contain healthcare costs.
BG Medicine’s first commercialized product is BGM Galectin-3™, an in vitro diagnostic blood test that identifies patients with an inherently progressive form of heart failure resulting from cardiac fibrosis.

For European customers, the BGM Galectin-3 test can be ordered through our European distributor, Kordia: www.kordia.com, Tel.: +31 (0) 71 523 10 50, Email: info@kordia.com

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ROCHE

Grenzacherstrasse 124, Basel, 4070, Switzerland
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RELYPSA, INC.

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Dr. Gerrit Klaerner, President

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Servier has developed drugs for the treatment of hypertension, cardiac ischemia, and heart failure. Procoralan (ivabradine), Vastarel MR (trimetazidine), Coversyl (perindopril), Coveram (perindopril-amlodipine), Preterax (perindopril-indapamide), and Natrilix SR (indapamide) are our major cardiovascular drugs.
Procoralan (ivabradine), the first If inhibitor on the market, is indicated for the symptomatic treatment of chronic stable angina. The SHIFT study of the efficacy of Procoralan in the management of heart failure patients was presented at the ESC 2010 congress and is currently being evaluated by the EMA for approval in this new indication.

In addition, Servier is also developing new drugs in the cardiovascular field, which accounts for 60% of its turnover.

For more information, please visit http://www.servier.com

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REGISTRATION FEE
On-site registration: 750 euros

Participant registration fee includes:
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Access to the Clinical Gathering Space
Congress materials
Lunches on December 2nd and 3rd, 2011
Daily coffee breaks
Congress Dinner on Friday December 2nd, 2011, from 8.15 pm
at George C. Marshall Center in Hotel Talleyrand, 2 rue de Saint-Florentin, 75001 Paris

Opening hours of the welcome desk
Thursday 1 December, 2011: 09:00 am - 07:00 pm
Friday 2 December, 2011: 08:00 am - 07:00 pm
Saturday 3 December, 2011: 07:30 am -07:00 pm

CLINICAL GATHERING SPACE
The Clinical Gathering Space will be located on the mezzanine level
Morning coffee breaks will take place in the Plenary Sessions foyer
Afternoon coffee breaks will take place on the mezzanine level
Lunch boxes will be served in the Plenary Sessions at 12:30 and 12:15 pm on December 2nd and 3rd

OFFICIAL LANGUAGE
The official language of the meeting is English.

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