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CBI's 4th Annual

Cardiac Safety Assessment Summit

The Latest Approaches in the Evaluation of Drugs that Affect Heart Rate, Blood Pressure, QT Prolongation and Other CV Safety Related Issues

January 12-13, 2010 • The Madison, A Loews Hotel • Washington, DC

CONFERENCE CO-CHAIRS

Lawrence Z. Satin, M.D., F.A.C.C.,
Chief Medical Officer,
Cardiocore

Daniel Bloomfield, M.D.,
Executive Director,
Cardiovascular Clinical Research;
Chair, Cardiac Safety Board,
Merck Research Laboratories

FDA ADDRESS

"How to Analyze and Interpret Adverse Event Data"

Thomas A. Marciniak, M.D., Medical Team Leader, Cardiovascular & Renal Products,
Food and Drug Administration

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- Understand the FDA's perspective on adverse event data analysis and interpretation
- Learn how preclinical safety testing can modulate early clinical programs
- Review the various benefits available by analyzing continuous electrocardiographic recordings (Holter monitoring) in early exploratory development
- Prevent catastrophic late stage failures, reduce the total cost of cardiac safety assessment programs and avoid TQT studies in the late stages of development
- Gain a regulatory perspective on cardiac safety assessments for oncology therapies
- Hear about the new FDA guidance in evaluating cardiovascular risk in new anti-diabetic therapies
- Explore how to analyze and interpret data from cardiovascular safety studies using more standardized and consistent methods
- Examine drugs that affect heart rate and explore strategies involved in evaluating their overall cardiac safety liability
- Review the diverse therapeutic approaches for treating patients with atrial fibrillation
- Learn how S-troponins can be used as a screening tool in early clinical development

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"Excellent discussion, topical topics, good speakers, brought me to the state-of–art in only two days." — 2009 Attendee, Philip Kastner, Director Pharmaceutical, **Alcon Research Ltd.**

MAIN CONFERENCE

Day One — Tuesday, January 12, 2010

7:30 *Main Conference Registration*

8:30 *Chairman's Opening Remarks*

Lawrence Z. Satin, M.D., FACC, Chief Medical Officer, **Cardiocore**

With over forty years of distinguished experience, Dr. Satin is one of the world's leading research cardiologists. He is an internationally recognized thought leader in cardiac safety testing for clinical trials. Early in his career, Dr. Satin worked with Dr. Norman Holter (inventor of the Holter monitor) analyzing the cardiac responses of astronauts in the NASA space program. In 1992, he helped pioneer the centralized cardiac testing industry, founding one of the first cardiac core labs, ***Central Cardiac Testing****. When the FDA published its new guidance for QT analysis in 2003, Dr. Satin founded Cardiocore, a leading-edge core lab designed to help sponsors efficiently meet the FDA's most challenging requirements.*

FDA ADDRESS

8:45 **How to Analyze and Interpret Adverse Event Data**

The bottom line in cardiac safety is not electrical variations, but adverse clinical events. Clinical data are messy, difficult to analyze and subject to varying interpretations. This address covers the analysis and interpretation of adverse event data from the perspective of an FDA reviewer. It includes actual examples (some masked, some open) of approaches to and problems with clinical trial adverse event data. Benefits of this address include:

- Understanding an FDA perspective on adverse event data analysis and interpretation
- Identifying a limitation of current systems for collecting adverse event data
- Recognizing some pitfalls in adverse event reporting and coding
- Accommodating the paradigm shift between efficacy and safety reviews

Thomas A. Marciniak, M.D., Medical Team Leader, Cardiovascular & Renal Products, **Food and Drug Administration**

9:30 **Use Preclinical QT Data to Impact Clinical Study Design, Decision Making and Clinical Validation of Preclinical Models**

This session explores how preclinical testing results can be used to guide an early clinical development program with respect to the intensity and approaches to early CV safety data collection and analysis. Using the paradigm presented, the early human testing approach can be modulated to most efficiently determine the presence or absence of a safety signal in a manner that maximizes efficiency and is mindful to resource utilization.

- Understand how preclinical safety testing can modulate the early clinical program
- Design the most efficient early clinical trials
- Help make go/no go decisions as early as possible
- Better understand the preclinical safety testing results

Philip Sager, M.D., Vice President, Clinical Research, **Gilead Sciences, Inc.**

10:15 *Networking and Refreshment Break*

10:45 **Cardiac Safety Strategies in Early Clinical Development**

This session reviews the various benefits of analyzing continuous electrocardiographic recordings (Holter monitoring) in early exploratory development. Key cardiac safety information, including the compounds potential for arrhythmogenic effects, may be established in first in human, single ascending dose, multiple ascending dose and maximum tolerated dose trials, prior to the design and conduct of a thorough QT study.

Lawrence Z. Satin, M.D., FACC, Chief Medical Officer, **Cardiocore**

11:30 **Advanced Cardiac Safety — De-Risking Drug Candidates in Early Clinical Development and Preventing Late Stage Failures**

Approximately 10% of late stage compounds (Phase IIb – Phase III) experience failure in the FDA-mandated TQT studies to conclusively characterize drug's effect on cardiac repolarization. These failures lead to delays in development programs, mounting costs, loss of revenue and in some cases may lead to termination of the drug in development. This problem stems from very well known limitations of the conventional cardiac safety approaches, i.e., high rate of false-positives and negatives and very high cost of the precise measurements with conventional analysis techniques. A significant opportunity exists to cost-effectively and significantly reduce late stage cardiac safety risks in early clinical development. This opportunity is often overlooked in development programs, causing downstream issues ranging from false positives to un-interpretable QT study results. By applying advanced, validated and FDA accepted ECG analyses, a number of critical cardiac safety questions can be answered in small studies (FIH/SAD/MAD) and help drug developers avoid costly downstream problems. In this session, attendees learn that by applying advanced techniques and proactive cardiac safety assessment strategies, drug developers can:

- Prevent the catastrophic late stage failures
- Reduce the total cost of the cardiac safety assessment programs and in some cases, avoid TQT studies in the late stages of development

Sasha Latypova, Executive Vice President, **iCardiac Technologies, Inc.**

12:15 *Luncheon*

1:30 **Cardiac Safety Testing for Oncology Therapies**

This presentation provides a regulatory perspective on cardiac safety assessments for oncology therapies, with attention to QT prolongation, haemodynamics and ventricular performance. Case studies from drug submissions are presented to illustrate the advantages and limitations of various cardiac safety assessment strategies.

Case Studies

- QT prolongation
- Haemodynamic effects
- Contractility

Colette Strnadova, Ph.D., Senior Scientific Advisor, Therapeutic Products Directorate, **Health Canada**

2:15 **Cardiac Toxicity and its Management in Oncology Settings**

This session examines rhythm disturbances, ischemic changes, contractility issues, blood pressure issues and potential risk mitigation strategies. The presentation also looks at how to make a benefit/risk decision to determine the acceptance of the safety risk for further development.

Case Studies

Kamal Shah, M.D., Head, Global Trials Safety Surveillance, **Celgene Corporation**

3:00 *Networking and Refreshment Break*

3:30 **Cardiovascular Safety of Exenatide BID — An Integrated-Analysis from Long-term Controlled Clinical Trials in Subjects with Type 2 Diabetes**

Exenatide BID (Ex) is a first-in-class GLP-1 receptor agonist. It is an anti-diabetic medication associated with weight loss, improvements in lipid profile, reduction in blood pressure and a low risk of hypoglycemia in the absence of an SFU. To evaluate cardiovascular (CV) safety a meta-analysis of CV events was performed on an integrated database of 12 completed randomized controlled clinical trials ranging from 12 to 52 weeks to compare the relative risk (RR) of CV events with Ex (5 & 10 µg) versus a pooled comparator group (PC) treated with either placebo or insulin. CV events included: Stroke, myocardial ischemia, myocardial infarction, cardiac mortality, arrhythmia, revascularization procedures and congestive heart failure. Events were identified by preferred terms according to the Medical Dictionary for Regulatory Activities (MedDRA 11.0).

Case Studies

- Illustrate implementation of the new FDA guidance document in evaluating CV risk in new anti-diabetic therapies
- An overview of cardiovascular safety of exenatide BID, a first-in-class GLP-1 receptor agonist
- An overview of the clinical trials of exenatide that provided the basis for the meta-analysis
- Selection of the CV endpoints for the meta-analysis
- Identify the benefits and pitfalls of the meta-analysis approach

Irina Yushmanova, M.D., Senior Director, Global Safety, **Amylin Pharmaceuticals, Inc.**

4:15 **Assessment of Drugs that Affect Blood Pressure**

PANEL

Blood pressure (BP) effects as part of the pharmacology of a drug or as an off-target effect have recently generated a lot of attention based on late stage development withdrawals (e.g. torcetrapib) and increasing safety concerns with other drugs, such as beta-agonists, PDE4 inhibitors in combination with nitrates, alpha blockers). Blood pressure as a parameter can easily be measured and could be incorporated in early clinical trials in healthy volunteers. It may therefore appear tempting to request repeat BP measurement on a routine basis for all drugs, similar to a thorough QT study. The panel and the audience discuss the value and cost implications of such an approach.

Moderator: Börje Darpö, M.D., Ph.D., Pharmaceutical Consultant, **Sweden**

Panelists: *Gary Gintant, Ph.D., Senior Group Leader, Department of Integrative Pharmacology,* **Abbott**

Kamal Shah, M.D., Head, Global Trials Safety Surveillance, **Celgene Corporation**

Daniel Bloomfield, M.D., Executive Director, Cardiovascular Clinical Research; Chair, Cardiac Safety Board, **Merck Research Laboratories**

5:00 *Close of Day One*

5:00-6:00 ***Networking, Wine & Cheese Reception***

Join colleagues and friends in a relaxed setting.

Photo by: Photolink / Getty Images

Day Two — Wednesday, January 13, 2010

7:30 *Continental Breakfast*

8:00 *Chairman's Review of Day One*

Daniel Bloomfield, M.D., Executive Director, **Cardiovascular Clinical Research;** *Chair, Cardiac Safety Board,* **Merck Research Laboratories**

Dr. Bloomfield currently works at Merck Research Laboratories as an Executive Director in Clinical Cardiovascular Research and is responsible for drug development for hypertension, arrhythmias and heart failure. Dr. Bloomfield joined Merck Research Laboratories in 2003 in Clinical Pharmacology, was involved in and co-chaired a number of early development teams. He has chaired the QT Task Force (multifunctional group of over twenty individuals involved in all aspects of Merck's response to the E14 guidance), created the Integrated Pre-clinical and Clinical Cardiovascular Safety Team (CVST) and the Cardiac Safety Board. Dr. Bloomfield is currently co-chair of the ***Cardiac Safety Research Consortium****, a public private partnership with the FDA, academia and industry devoted to advancing scientific knowledge on cardiac safety for new and existing medical products by building a collaborative environment based upon the principles of the FDA's Critical Path Initiative as well as other public health priorities.*

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8:15 **Assessment of Drugs that Affect Heart Rate — A Simple yet Complex Story**

With advancements in cardiac monitoring and continued interest in cardiac safety, more attention is being paid to the assessment of heart rate as part of safety evaluations of all therapeutic products. This session specifically looks at drugs that affect heart rate and explores strategies involved in evaluating their overall cardiac safety liability.

- Recognize complexity of this simple response
- Explore potential implications
- Discuss specific drug examples

Gary Gintant, Ph.D., Senior Group Leader, Department Integrative Pharmacology, **Abbott**

9:00 **Appropriate Methods for Individualized Heart Rate Correction**

Calculation of individually corrected QTc intervals has been implemented into a number of thorough QT studies but incorrect technologies have frequently been used in designing the individual corrections. The session describes the physiologic background of the correct technologies, step-by-step demonstration of their design and discusses advantages achieved by their use.

- Individuality of drug-free QT/RR relationship
- Data needed for accurate QT/RR models and assessment of QT/RR stability
- Distinction of QT/RR adaptation and QT/RR hysteresis, correction for hysteresis
- Reduction of QTc variability by appropriate QT/RR modeling

Marek Malik, Ph.D., M.D., DSc, FACC, FESC, FHRS, Professor of Cardiac, Electrophysiology, Chairman, **St. Paul's Cardiac Electrophysiology, London**

10:15 **Clinical Validation of Automated ECG Reading Methods**

PANEL

This panel examines the comparison between human readers and automated ECG measurements. The panel also discusses the evolving approaches to automated QT analyses and their impact on the performance of TQT studies.

Moderator: Philip Sager, M.D., Vice President, Clinical Research, **Gilead Sciences, Inc.**

Panelists: Eric W. Lewis, M.D., Director Clinical Pharmacology, **GlaxoSmithKline**

Börje Darpö, M.D., Ph.D., Pharmaceutical Consultant, **Sweden**

Nenad Sarapa, M.D., FCP, Head of Clinical Pharmacology-Oncology, **Hoffman-La Roche**

Sasha Latypova, Executive Vice President, **iCardiac Technologies, Inc.**

11:00 **Exposure-Response Relationships for Cardiovascular Safety Studies**

This session examines the importance of determining exposure-response in CV safety trials. An overview of PK/PD data interpretation is provided along with PK/PD data analysis methods that are helpful and those that are not. Benefits of this session include how to analyze and interpret data from CV safety studies using more standardized and consistent methods.

Luana Pesco Koplowitz, M.D., Ph.D., FCP, FFPM, President, Chief Medical & Scientific Officer, **DUCK FLATS Pharma, LLC**

11:45 *Luncheon*

1:00 **Potential Cardiac Safety Issues Associated with Novel Treatments for Atrial Fibrillation**

Atrial fibrillation is the most common arrhythmia experienced in the adult population and its incidence continues to increase. There is growing interest in the development of novel therapeutic approaches to treating patients with atrial fibrillation that includes drugs, devices and new procedures including ablation. The treatment of atrial fibrillation has two major approaches — cardioversion of patients from atrial fibrillation to sinus rhythm and prevention of recurrent atrial fibrillation (or maintenance of sinus rhythm). A number of potential cardiac safety issues have arisen in the development of these novel therapeutic approaches to treating this very common and complex arrhythmia. This session provides an overview of these different issues and describes a potential collaborative approach towards addressing these issues that have been initiated by the Cardiac Safety Research Consortium.

- Review the diverse therapeutic approaches to treating patients with atrial fibrillation including drugs, devices and new procedures, including ablation
- Examine the potential cardiac safety issues that are relevant to the development of novel therapeutics designed to treat patients with atrial fibrillation
- Addressing issues that have been initiated by the Cardiac Safety Research Consortium

Daniel Bloomfield, M.D., Executive Director, **Cardiovascular Clinical Research;**
Chair, Cardiac Safety Board, **Merck Research Laboratories**

1:45 *Networking and Refreshment Break*

2:15 **Troponins as Safety Biomarkers in Drug Development**

The value of serum troponins has been well established for the diagnosis of myocardial infarction, in which often pronounced and long-lasting elevations are observed. Certain drugs can also exert direct cardiomyocyte toxicity, either acutely or after chronic and repeat use, as with doxorubicin. The role of troponins as safety biomarkers in early, exploratory clinical trials is discussed, as well as predictive value and limitations with different assays. Delegates benefit from this presentation through learning about:

- Drugs that exert direct cardiomyocyte toxicity and how these were identified during clinical development
- How S-troponins can be used as a screening tool in early clinical development
- How to improve the predictive value of this safety biomarker

Börje Darpö, M.D., Ph.D., Pharmaceutical Consultant, **Sweden**

3:00 *Close of Conference*

Who Should Attend:

You will benefit from attending this event if you are a CMO, CSO, Medical Director, Executive or Senior Level Vice President or Director, Scientist or Investigator with responsibilities or involvement in the following areas:

- Clinical Operations
- Clinical Pharmacology
- Clinical Development
- Cardiac Safety
- Safety Surveillance
- Clinical Program Management
- Translational Research/Medicine
- Biostatistics
- Cardiology
- Clinical Studies
- Clinical Research
- Clinical Safety
- Drug Safety
- Clinical Project Management
- Clinical Affairs
- Experimental Medicine
- Regulatory Affairs
- Oncology

This conference will also benefit consultants, contract research organizations, technology providers, ECG Labs, service providers, data management companies and industry analysts working in cardiac safety.

Acclaim from Previous Conference Attendees:

"One of the best cardiac safety conferences I have attended."

– Corina-Dana Dota, M.D., ECG Centre Director, Co-Chair, QT/Arrhythmia Safety Knowledge Group, **AstraZeneca Research and Development, Mölndal, Sweden**

"Excellent opportunity to access cutting edge application and implementation of testing strategies and areas identified for development of cardiac safety."

– Joni Love, Nurse Consultant, **NIH**

"Necessary for understanding TQT study."

– Cindy Green, Assistant Professor Biostatistics, **COResearch**

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Cardiocore has provided superior centralized cardiac testing services to the pharmaceutical industry for 17 years. Services include centralized electrocardiography (ECG), Holter monitoring, echocardiography (ECHO), multigated acquisition scans (MUGA), protocol development and statistical analysis. The company is experienced in cardiac safety and efficacy testing in Phase I-IV and Thorough QT clinical trials. These services are supported by the company's advanced data management system featuring the proprietary HolterGateway™ and CardioPortal™. Cardiocore's U.S. headquarter is located in Bethesda, Maryland, its West Coast office is located in San Francisco, California and its European subsidiary, Cardiocore Limited, is located in London, England. Visit www.cardiocore.com for more information.

About Our Supporting Organization:

The CSRC is a public-private partnering structure to cultivate, develop, launch and implement pre-competitive programs targeting key issues in the evaluation of cardiac safety during the development of drugs and devices. The CSRC places its emphasis on pan-stakeholder collaboration between leaders in academics, industry and regulatory agencies to develop more effective strategies and processes related to the evaluation of cardiac safety. The CSRC was established in 2006 under a Memorandum of Understanding between the FDA and Duke University.

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Conference Highlights Include:

- Cardiac toxicity and its management in oncology settings
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- Assessment of drugs that affect blood pressure
- A review of the diverse therapeutic approaches to treating patients with atrial fibrillation
- Clinical validation of automated ECG reading methods

FDA Address

"How to Analyze and Interpret Adverse Event Data"
Thomas A. Marciniak, M.D., Medical Team Leader, Cardiovascular & Renal Products, **Food and Drug Administration**

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