Cardiac Safety Research Consortium

INTERNATIONAL CONSORTIUM for INNOVATION & QUALITY in PHARMACEUTICAL DEVELOPMENT

Can QT Assessment in Early Clinical Development be used to replace the TQT Study – Presenting Results from the Prospective IQ-CSRC Clinical Study

White Oak Facility, FDA Headquarters • Silver Spring, Maryland• December, 12 2014
7:30am-5:00pm

Agenda

7:30-8:00am- Registration and Continental Breakfast

8:00-9:20am- Session 1: The context and the concept of 'Early ECG assessment'
Session chair and moderator: Borje Darpo

- Background and objectives of the IQ-CSRC project-**Borje Darpo,** *iCardiac* (20min)
- Regulatory background (e.g. From the thorough QT study to newer ways of confidently assess ECG effects of new drugs)- **Doug Throckmorton**, *FDA*(20min)
- Exposure response analysis as an evolving tool for regulatory decision making for the assessment of ECG effects of new drugs- **Kevin Krudys,** *FDA*(20min)
- Study design and choice of drugs- **Nenad Sarapa,** Bayer HealthCare Pharmaceuticals (20min)

9:20- 9:45am-Coffee break

9:45-12:15pm- Session 2: Results and interpretations of the study
Session chair: Nenad Sarapa

- Results of the study:
  - Part 1: Statistical considerations and methods- **Georg Ferber,** *Statistik Georg Ferber GmbH* (15min)
  - Part 2: Results- **Steve Riley,** *Pfizer* (30min)
- FDA's analysis and interpretation of the data – **Jiang Liu,** FDA (30min)
- Panel discussion on results with speakers and invited panelists (75min)
  Moderator: Steve Riley
  - **Corina Dota,** *AstraZeneca*
  - **Catherine Ortemann-Renon,** *Sanofi-Aventis*
  - **Venkat Jarugula,** *Novartis*
  - **Christine Garnett (ex-E14),** *Certara*
  - **Qianyu Dang,** Biostatistics, FDA
  - **Yaning Wang, FDA**
  - **Jiang Liu,** FDA,
  - **Lars Johannesen,** *FDA*

12:15- 1:30pm- Lunch

1:30-3:30pm- Session 3: Clinical and regulatory implications of the study
Session chair and moderator: Christine Garnett

- The sponsor's perspective: How can these data help us design phase 1 SAD/MAD studies to generate ECG data to replace the TQT study?- **James Keirns**, *Astellas* (15mins)
  - FDA perspective- **Norman Stockbridge** (15min)
  - Cardiologist's perspective- **Peter Kowey,** *Lankenau Heart Group* (15min)

Panel discussion on clinical and regulatory implications of study results with presenters and invited panelists.
Moderator: Borje Darpo

- **James Keirns,** *Astellas*
- **Dan Bloomfield,** *Merck*
- **Philip Sager,** *Stanford University/Sager Consulting Experts*
- **Charles Benson,** *Eli Lilly*
- **Corina Dota,** *AstraZeneca*
- **Kaori Shinagawa,** *PMDA,*
- **Colette Strnadova,** *Health Canada,*
- **Norman Stockbridge,** *FDA*
- **Bob Temple,** *FDA*
- **Doug Throckmorton,** *FDA*
- **Krishna Prasad,** *MHRA*
- **Christine Garnett (ex-E14),** *Certara*

3:30- 4:00pm- Coffee break

4:00-5:00pm- Session 4: Next steps
Session chair and moderator: James Keirns

- How do the results from the IQ-CSRC study impact the ICH E14 clinical guidance?- **Norman Stockbridge,** *FDA* (15min)
- Open-access research: The CSRC ECG warehouse for continuous waveforms- **Cindy Green**, *CSRC and DCRI* (15min)
- How does the CiPA initiative relate to the IQ-CSRC project?- **Philip Sager,** *Stanford University/Sager Consulting Experts* (15min)
- Concluding remarks - The path forward- **Christine Garnett**, *Pharsight Consulting Services, Certara* (15min)