MOVING TOWARDS BETTER PREDICTORS OF DRUG-INDUCED TORSADES DE POINTE (TDP)

November 2-3, 2005

Doubletree Hotel
Crystal City, Virginia

Workshop Program

November 2, 2005

8:00    Workshop Welcome and HESI Overview                  Dr. Michael Holsapple
        HESI

8:15    Background / Workshop Objectives                  Dr. Alan Bass
        Schering-Plough Research Institute

<table>
<thead>
<tr>
<th>Session I. Molecular and Cellular Biology Underlying TdP</th>
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| 8:30    Cellular Biology                                 Dr. Dan Roden
          Vanderbilt University                             |
| 9:00    Trafficking of Ion Channels                      Dr. Craig January
          University of Wisconsin                            |
| 9:30    Calcium Cycle Modulation                          Dr. Guy Salama
          University of Pittsburgh                           |
| 10:00   Session I Panel Discussion                         |
| 10:30   Break                                              |

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<tr>
<th>Session II. Dynamics of Periodicity</th>
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| 10:45   Influence of Autonomic Nervous System               Dr. Anthony Fossa
          Pfizer Global R&D                                     |

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<tr>
<th>Session III. Models of TdP Proarrhythmia</th>
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| 11:15   In Vivo Models                                    Dr. Marc Vos
          University Medical Center Utrecht                    |
| 11:45   In Vitro Models                                   Dr. Chris Lawrence
          Astra-Zeneca Pharmaceuticals                           |
| 12:15   Sessions II and III Panel Discussion               |
Session IV. Predictive Value of Pre-Clinical Models

2:00  Pharma Perspective  
Dr. Tim. Hammond  
Astra-Zeneca Pharmaceuticals

2:30  FDA Perspective  
Dr. John Koerner  
US Food & Drug Administration

Session V. Key Considerations for Demonstrating Utility of Pre-Clinical Models

3:00  FDA Perspective  
Dr. Doug Throckmorton  
US Food & Drug Administration

3:30  CHMP Perspective  
Dr. Klaus Olejniczak  
Federal Institute for Drugs and Devices

4:00  Break

4:15  Japanese (PMDA) Perspective  
Dr. Atsushi Sugiyama  
University of Yamanashi

4:45  Clinical Perspective  
Dr. Phillip Sager  
Astra-Zeneca Pharmaceuticals

5:15  Sessions IV and V Panel Discussion

5:45  Day 1 Wrap-Up / Day 2 Expectations  
Dr. Alan Bass

6:00  Adjourn

6:30  Workshop Reception

November 3, 2005

8:30  Breakout Session Overview  
Mr. Karluss Thomas

8:45  Facilitated Breakout Sessions

Each workshop participant will spend four hours in one session. Each session will have facilitator(s) and rapporteur(s).

Session I - Molecular and Cellular Biology Underlying TdP  
Co-Chairs: Craig January and Dan Roden  
Rapportuers: TBD

Session II - Dynamics of Periodicity  
Chair: Derek Leishman  
Rapportuers: Jean-Pierre Valentin and Diane Garnes

Session III - Models of TdP Proarrhythmia  
Co-Chairs: Wilhelm Haverkamp and Marc Vos  
Rapportuers: Hal Feldman and Alexander Breidenbach
<table>
<thead>
<tr>
<th>Time</th>
<th>Activity</th>
<th>Notes</th>
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<tbody>
<tr>
<td>1:00</td>
<td>Lunch</td>
<td></td>
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<tr>
<td>2:30</td>
<td>Breakout Session Reports</td>
<td>Facilitated Discussion</td>
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<td>Facilitator and/or rapporteur from each session will lead workshop participants through each topic. Summary for each session will include identification of consensus issues and development of priorities for next steps.</td>
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<tr>
<td>4:30</td>
<td>Break</td>
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<tr>
<td>4:45</td>
<td>Workshop Summary and Next Steps</td>
<td>A. Bass</td>
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<td>5:00</td>
<td>Adjourn</td>
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