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EMEA/EFPIA WORKSHOP ON BIOMARKERS

15 DECEMBER 2006

3 A

Chairpersons: Prof Bruno Flamion/Dr Andre W. Broekmans

AGENDA

Date 15 December 2006
Doc. Ref: EMEA/262936/2006

9.00 Chairpersons welcome

Introduction

9.10 Prof Bruno Flamion (CHMP/SAWP) Biomarkers: EMEA initiatives and SAWP
Ministry of Public Health Medicines experience
Belgium

SESSION I: Oncology

9.30 Dr Hans Winkler Biomarker in Oncology: Research and early
Johnson and Johnson development

9.50 Dr Andrew Hughes/Dr Andrew Stone Converting a biomarker to a surrogate – What should
AstraZeneca it take: AstraZeneca priority list

10.10 Dr Rafal Dziadziuszko Pharmacogenomic markers in EGFR-targeted
University of Colorado Cancer therapy of lung cancer
Center, Denver, USA

10.30 Dr Bertil Jonsson (SAWP) Oncology-Regulatory perspective
Läkemedelsverket, Sweden

10.45 Q&A session Oncology

11.15 Coffee break

SESSION II: Cardiovascular

11.30 Dr Bill Vennart Imaging Biomarkers: Utilisation for the purpose of
Pfizer registration



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| 11.50 | Dr Gonzalo Calvo Rojas (CHMP)
Agencia Española del Medicamento
y Productos Sanitarios, Spain | Cardiovascular-Regulatory perspective |
| 12.05 | Q&A session Cardiovascular | |

SESSION III: Osteoporosis/Osteoarthritis

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| 12.30 | Dr Dominique Ethgen
GSK | Potential biomarkers to be used for
osteoporosis drug development: opportunities and
challenges for validation |
| 12.50 | Dr Frits Lekkerkerker (CHMP)
College Ter Beoordeling van
Geneesmiddelen, The Netherlands | Osteoporosis-Regulatory perspective |
| 13.05 | Q&A session Osteoporosis | |
| 13.30 | Lunch Break | Buffet Room 3B |

SESSION IV: General

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| 14.15 | Dr Solange Rohou
AstraZeneca | EPARs survey/similarities and divergences
between Europe and the USA |
| 14.35 | Prof. Klaus Lindpaintner
Roche | IMI strategic research agenda as it applies
to surrogates |
| 14.55 | Dr Charles T. Benson
Eli Lilly | Biomarker Validation: Why, which, and how? |
| 15.15 | Dr Geoff Barton
GSK | EFPIA position paper proposals |
| 15.35 | Coffee break | |
| 16.00 | Discussion session focussing on expectations, collaboration and pre-competitive research | |
| 17.00 | Chairman's closing remarks and future actions | |