

SMi presents the 16th annual

Pain Therapeutics

Capturing the latest developments and innovations to
accelerate market access

HOLIDAY INN KENSINGTON FORUM, LONDON, UK

23RD - 24TH
MAY
2016

CHAIRS FOR 2016

- **Dr Steven Kamerling**, Therapeutic Area Head for Pain & Inflammation, **Zoetis**
- **Dr Stephen Doberstein**, Senior Vice President and Chief Scientific Officer, **Nektar Pharmaceuticals**

FEATURED SPEAKERS

- **Dr Neelima Khairatkar Joshi**, Sr Vice President, **Glenmark Pharmaceuticals**
- **Dr Richard Butt**, Senior Director, Research Project Leader, Clinical Research, **Pfizer**
- **Dr Ozgur Sancak**, Global Medical Science Lead – Pain, **RB**
- **Dr Thomas Christoph**, Senior Director, Head of Pain Pharmacology, **Grunenthal GmbH**
- **Dr Chao Chen**, Therapy Area Head, **GSK**
- **Dr Catherine Stehman-Breen**, VP Clinical Sciences, **Regeneron**

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HIGHLIGHTS in 2016

- Presentations on strategies to minimise risk for opioid dependence
- Discover **Pfizer's** achievements for the past year on voltage gated sodium channels
- Learn about **Glenmark's** experience on pain drug discovery
- Join the debate in interactive panel discussion on **medical incidents in experimental drug trials**
- Hear presentations on cutting edge clinical developments from industry leaders and scientific pioneers

PLUS AN INTERACTIVE HALF-DAY POST-CONFERENCE WORKSHOP | WEDNESDAY 25TH MAY 2016, HOLIDAY INN KENSINGTON FORUM, LONDON, UK

Animal models for the study of compounds in pain therapy: From screening to translational models

Hosted by: **Dr Sigal Meilin**, Chief Scientific Officer, **MD Biosciences, Innovalora Ltd**

8:30 - 12:30

www.pain-therapeutics.co.uk

Register online or fax your registration to +44 (0) 870 9090 712 or call +44 (0) 870 9090 711



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8.30 Registration & Coffee

9.00 **Chairman's Opening Remarks**
Dr Steven Kamerling, Therapeutic Area Head for Pain & Inflammation, Zoetis

DRUG DEVELOPMENT & MECHANISMS

9.10 **OPENING ADDRESS**
Pain Drug Discovery: Learnings over a decade?

- Current treatments and gaps
 - What to target –enzymes? receptors?
 - Where to target – central of peripheral?
 - New analgesics – myth or reality?
- Dr Neelima Khairatkar Joshi**, Sr Vice President, Glenmark Pharmaceuticals

9.50 **Understanding ligand recognition on the molecular level**


- Identification of NF770 as a potent and competitive antagonist for P2X2 (purinergic ion channel)
- Double mutant cycle analysis and protein-ligand interactions
- Protein modeling and simulation for compound design

Dr Achim Kless, Associate Scientific Director, Grunenthal GmbH

10.30 Morning Coffee

11.00 **MDB010506: Discovery of a novel, highly effective small molecule compound for neuropathic pain; from phenotypic screening to full, preclinical lead validation**

- The use of in vivo phenotypic screening for the identification of pharmaceutically relevant activity
- Description of the preclinical program for the development of the candidate compound MDB010506
- Summary of results

Dr Sigal Meilin, Chief Scientific Officer, MD Biosciences, Inovalora Ltd 

11.40 **Challenges and opportunities in topical ibuprofen development**

- Topical vs transdermal delivery
- Local tolerance and skin irritation
- Clinical models for investigating efficacy of topical analgesics

Dr Ozgur Sancak, Global Medical Science Lead – Pain, RB

12.20 Networking Lunch

TRANSLATIONAL APPROACH

1.30 **Current questions to animal models of pain**

- Models
- Readouts
- Translation

Dr Thomas Christoph, Senior Director, Head of Pain Pharmacology, Grunenthal GmbH

2.10 **Pain, Osteoarthritis & Translational Veterinary Medicine**

- Medical management of osteoarthritis and pain in people and pets
- What can be learned across species with regard to models and spontaneous diseases: translational veterinary medicine
- Focus on pharmaceutical and biopharmaceutical approaches

Dr Steven Kamerling, Therapeutic Area Head for Pain & Inflammation, Zoetis

2.50 Afternoon Tea

3.20 **Reproducibility of a battery of human evoked pain tests to determine the pharmacological profile of novel analgesic drugs**

- A battery of human evoked pain tests that can be used to profile new analgesic drugs and to determine the active drug dose range in humans prior to phase II
- Unique profile for different reference analgesic compounds that was compatible with expected pharmacology
- Reproducibility of the pharmacological effects and pain test battery profile of different analgesic compounds that were used as positive controls in four phase I studies

Geert Jan Groeneveld, Research Director Neurology & Pain, Centre for Human Drug Research



4.00 **Translational biomarker for studying target engagement of ion channels in peripheral nerve**

- Ion channels are crucial in controlling the excitability of peripheral nerves and action potential propagation.
- Different subtypes of sodium channel are key for action potential propagation in different subtypes of sensory neurons
- Potassium channels and hyperpolarization-activated cyclic nucleotide-gated contribute to firing pattern of axons
- Nerve excitability profiling (NEP) allows study of these channels in rodents and primates including humans in vivo and in vitro
- NEP can investigate the effect of sodium channel blockers on transient and persistent currents and state- and use-dependency and tonic blocks

Martin Koltzenburg, Chair of Clinical Neurophysiology, University College London

4.40 **Human Tissue in pain research**

- Human neuroma tissue in studies of neuropathic pain
 - Human tooth pulp as a model of inflammatory pain
 - Correlation of clinical symptoms with specific markers
- Fiona Boissonade**, Head of Neuroscience Research Group, The University of Sheffield

PANEL DISCUSSION

5.20 **Medical incidents in experimental drug trials**

- Clinical trial methodology
- Challenges facing the current methods
- Medical exams procedure
- Reviews and recommendation

Moderator: Steven Kamerling, Therapeutic Area Head for Pain, Inflammation and Oncology, Zoetis

Panelists:

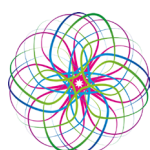
Thomas Christoph, Senior Director, Head of Pain Pharmacology, Grunenthal GmbH
Chao Chen, Therapy Area Head, Glaxosmithkline
Fiona Boissonade, Head of Neuroscience Research Group, The University of Sheffield
Martin Koltzenburg, Chair of Clinical Neurophysiology, University College London



6.00 **Chairman's Closing Remarks and Close of Day One**

Register online at www.pain-therapeutics.co.uk

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CHDR
 Centre for Human Drug Research

Since 1987, **CHDR** has developed into a unique research organisation specialising in early phase studies which combines knowledge and academic collaborations with operational excellence in clinical trial services. CHDR's strong track record in analgesic and pain research allows us to offer an efficient route towards proof of concept in patients. www.chdr.nl

MD Biosciences, Inc., is a leading development partner in the area of neurodegenerative diseases and pain therapeutics. With nearly 20 years of preclinical experience, MD Biosciences is experienced in all aspects of preclinical development, model development, the use of advanced biomarkers and predictive studies. The company has developed numerous methodologies, such as proprietary, translational models and histology techniques to support the successful development of candidate drugs through the preclinical phase into clinical phases. www.mdbiosciences.com

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8.30 Registration & Coffee

9.00 Chairman's Opening Remarks
Dr Stephen Doberstein, Senior Vice President and Chief Scientific Officer, **Nektar Pharmaceuticals**

OPIOID DEPENDENCE

OPENING ADDRESS

9.10 NKTR-181, A Novel mu-opioid Analgesic Designed for Inherent Low Abuse Liability

- Engineering brain entry rate of MOR agonists to reduce euphoria and abuse liability
- Maintaining mu-opioid receptor activity while modulating brain entry rate
- Preclinical to clinical translation of opioid characteristics

Dr Stephen Doberstein, Senior Vice President and Chief Scientific Officer, **Nektar Pharmaceuticals**

9.50 Strategies to minimise risk for opioid dependence

- The review of current strategies
- The use of prescription monitoring programmes
- Alternatives to opioid therapy

Prof Remigiusz Lecybyl, Consultant in Chronic Pain, **University Hospital Lewisham***

CLINICAL TRIALS & MODELS

10.30 Morning Coffee

11.00 Voltage gated sodium channels... new pain therapies

- Preclinical and clinical development of selective sodium channel blockers – Part 2
- What has been achieved since the last year?
- Results update from assessment of PF-05089771 in painful diabetic neuropathy
- Discussion of next steps in development

Dr Richard Butt, Senior Director, Research Project Leader, Clinical Research, **Pfizer**

11.40 Small fibre neuropathy and channelopathy: from pain relief to disease modification

- Overview of clinical presentations, advanced diagnostic techniques, and current pain treatments
- Clinical translation success in Phase II trials for pain and itch: p38 MAP kinase inhibitor Dilmapirod, Angiotensin II Type 2 receptor antagonist EMA401, and Trk A inhibitor CT327
- Use of capsaicin 8% patch Qutenza for pain relief and disease modification

Prof Praveen Anand, Professor of Clinical Neurology and Head, Centre for Clinical Translation, **Imperial College London**

12.20 Networking Lunch

1.30 Treatment of moderate to severe chronic pain

- Epidemiology of moderate to severe chronic pain
- Treatment options for treatment of moderate to severe chronic pain
- Emerging treatment options for treatment of moderate to severe chronic pain

Dr Catherine Stehman-Breen, VP Clinical Sciences, **Regeneron**

2.10 Design and Interpretation of Clinical Proof-of-Concept Trials for Pain Drugs

- Clinical proof of concept informs major investment decisions
- Conventional design and analysis reflect improvement opportunities
- Principles and examples will be presented to explore these opportunities

Dr Chao Chen, Therapy Area Head, Clinical Pharmacology Modelling & Simulation, **GSK**

PATIENT MONITORING

2.50 Afternoon Tea

3.20 Clinical trial population: Defining patients recruitment strategy

- Optimal population sample
- Study observations
- Post-study outcomes

Speaker will be announced shortly

PANEL DISCUSSION

4.00 Alternative approach in pain therapeutics

- Quantitative predictive analysis
- Pain threshold level
- Drug interaction mechanisms

Moderator: Dr Stephen Doberstein, Senior Vice President and Chief Scientific Officer, **Nektar Pharmaceuticals**

Panelists:

Sigal Meilin, Scientific Director, **MD Biosciences**

Achim Kless, Associate Scientific Director, **Grunenthal GmbH**

Catherine Stehman-Breen, VP Clinical Sciences,

Regeneron Pharmaceuticals Inc

4.40 Chairman's Closing Remarks and Close of Day Two

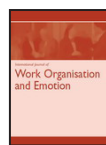
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HALF-DAY POST-CONFERENCE WORKSHOP

Wednesday 25th May 2016

Holiday Inn Kensington Forum, London, UK

8.30am – 12.30pm

Animal models for the study of compounds in pain therapy: From Screening to Translational Models

Hosted by: **Dr Sigal Meilin**, Chief Scientific Officer,
MD Biosciences, Innovalora Ltd

md biosciences.

Workshop overview:

Advances in preclinical animal models will be discussed to offer participants a view to different models, advantages and limitations of each model, examples of compounds being studied in such preclinical models. Highly predictive, translational pig models, developed at MD Biosciences will be presented to the audience using examples of compounds that succeeded in rodent models and either failed or succeeded in later human trials.

Why you should attend:

- The advantages and limitations of different animal models in the preclinical development phase for pain therapy
- Differentiation of compounds for the treatment of acute pain versus chronic or neuropathic pain
- Biomarkers and histology in pain models
- Advances in predictive, translational models in pain therapy; avoiding costly clinical phase trials

Agenda

8.30 Registration & Coffee

9.00 Opening remarks and introductions

9.10 Contribution of animal models to the research and understanding of pain

- Important milestones in the development of current animal models
- Differentiation of reflexive withdrawal response and general animal behavior in pain studies

9.50 Advantages and limitations of animal models in the development process for drug candidates in the area of pain

- Studies comparing systemic vs. topical pain-relief drugs using animal models
- How do rodent studies predict the PK/PD ratio in human application

10.30 Morning Coffee

11.00 The application of molecular markers in the study of drug candidates in pain

- Contribution of biomarker analysis to the understanding of the cross-talk between neuronal and other pathways, including the immune system
- The use of biomarkers for the better understanding of pain mechanism and the discovery of new targets for pain therapy

11.40 The application of swine models in studying drug candidates for the topical and/or local treatment of pain

- Translational, predictive swine models in the study of pain and pain therapy
- Presentation of a post-operative pain model in the swine

12.20 Closing remarks

12.30 End of workshop

About the workshop host:



Dr Meilin is a 25 year veteran of preclinical drug discovery and development in the area of neurological diseases, neuro-degeneration and pain. As Chief Scientific Officer at MD Biosciences, Innovalora, Dr Meilin developed leading expertise in the preclinical area through the study of many different compound classes, both small molecules and biologicals, in different disease models, applying advanced approaches to early stage drug discovery and development. Dr Meilin leads the collaborative drug discovery and development programs at MD Biosciences Innovalora.

About the organisation:

MD Biosciences, Inc., is a leading development partner in the area of neurodegenerative diseases and pain therapeutics. With nearly 20 years of preclinical experience, MD Biosciences is experienced in all aspects of preclinical development, model development, the use of advanced biomarkers and predictive studies. The company has developed numerous methodologies, such as proprietary, translational models and histology techniques to support the successful development of candidate drugs through the preclinical phase into clinical phases.

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FEBRUARY

Parallel Trade

8th - 9th February
Holiday Inn Kensington Forum, London, UK

Advances and Progress in Drug Design

15th - 16th February
Holiday Inn Kensington Forum, London, UK

RNAi Therapeutics

15th - 16th February
Holiday Inn Kensington Forum, London, UK

MARCH

Superbugs & Superdrugs - A Focus on Antibacterials

16th - 17th March
Holiday Inn Kensington Forum, London, UK

Paediatric Clinical Trials

16th - 17th March
Holiday Inn Kensington Forum, London, UK

APRIL

Asthma & COPD

11th - 12th April
Holiday Inn Kensington Forum, London, UK

Controlled Release

18th - 19th April
Holiday Inn Kensington Forum, London, UK

Adaptive Designs

18th - 19th April
Holiday Inn Kensington Forum, London, UK

Pre-Filled Syringes East Coast

25th - 26th April
Renaissance Woodbridge, New Jersey, USA

Lyophilization USA

27th - 28th April
Renaissance Woodbridge, New Jersey, USA

MAY

Alzheimer's

10th - 11th May
Holiday Inn Kensington Forum, London, UK

Clinical Trial Logistics

18th - 19th May
Holiday Inn Kensington Forum, London, UK

Pain Therapeutics

23rd - 24th May
Holiday Inn Kensington Forum, London, UK

ADC Summit 2016

23rd - 24th May
Holiday Inn Kensington Forum, London, UK

JUNE

Pre-Filled Syringes West Coast

6th - 7th June
Hyatt Regency Mission Bay, San Diego, USA

ADMET

13th - 14th June
Holiday Inn Kensington Forum, London, UK

Immunogenicity

13th - 14th June
Holiday Inn Kensington Forum, London, UK

BioBanking

20th - 21st June
Holiday Inn Kensington Forum, London, UK

JULY

Lyophilisation Europe

4th - 5th July
Holiday Inn Kensington Forum, London, UK

Allergies

6th - 7th July
Holiday Inn Kensington Forum, London, UK

Peptides

6th - 7th July
Holiday Inn Kensington Forum, London, UK

PAIN THERAPEUTICS CONFERENCE

Conference: Monday 23rd & Tuesday 24th May 2016, Holiday Inn Kensington Forum, London, UK Workshop: Wednesday 25th May, London

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