8.30  Registration & Coffee

9.00  Chair’s Opening Remarks
Kerrie Brady, Chief Business Officer, Centrexion Therapeutics
Michael Scherz, Founder and CEO, Metys Pharmaceuticals

9.10  OPENING ADDRESS
Clinical Development Issues for Management of Chemotherapy-Induced Symptoms of Peripheral Neuropathy
Theo Meert, ViroMed Co., Ltd.
William K. Schmidt, Iain Chessell, Kerrie Brady, Chief Business Officer, Centrexion Therapeutics

9.50  Opioid Sparing Outcomes: Practical Perspectives from 20 Years of Acute Pain Clinical Trials
Michael Scherz, Founder and CEO, Metys Pharmaceuticals
Neil Singla, Chief Executive Officer, Lotus Clinical Research

10.30  Morning Coffee

11.00  Gene Therapy for Painful Diabetic Neuropathy
William K. Schmidt, Vice President, Clinical Development, ViroMed Co., Ltd.

11.40  DEEP DIVE
New approaches and struggles to develop pain products
Theo Meert, Head of R&D Global Government Grant Office, Janssen Pharmaceutical

12.20  Networking Lunch

13.20  Round table discussion session
Topics:
- Public-Private Partnerships for Development of New Pain Medicines: Compare and Contrast Activities and Outcomes in US, Europe and Asia
- From lab to clinic- why are we not more successful in predicting clinical efficacy?
Iain Chessell, VP & Head, Neuroscience Innovative Medicines, AstraZeneca
Kerrie Brady, Chief Business Officer, Centrexion Therapeutics

- Why is Pain, a major health care problem, not getting the right attention?
Theo Meert, Head of R&D Global Government Grant Office, Janssen Pharmaceutical
- FDA are abandoning the 2014 draft guidance for developing novel treatments in neuropathic pain: will the new guidelines stimulate more and more creative drug development of innovative pain therapeutics
Michael Scherz, Founder and CEO, Metys Pharmaceuticals

14.40  Headache Therapy and relevance of fast formulations
Dalma Sugár, Global Medical Affairs Director, Reckitt Benckiser

15.00  Afternoon Tea

15.30  Found in translation: therapy for the disease of pain rather than nociceptive masking
Donald Manning, Chief Medical Officer, Adynxx, Inc.

16.10  Demonstration of significant pain relief in subjects with painful osteoarthritis of the knee with a novel anti-NGF, anti-TNFa bsicpecific fusion protein
Iain Chessell, VP & Head, Neuroscience Innovative Medicines, AstraZeneca

16.50  Chair’s closing remarks and close of day one

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8.30 Registration & Coffee

9.00 Co-Chair’s Opening Remarks
Kerrie Brady, Chief Business Officer, Centrexion Therapeutics
Michael Scherz, Founder and CEO, Melys Pharmaceuticals

OPENING ADDRESS

9.10 Molecular Neurosurgery – CNTX-4975 for Chronic Pain
• CNTX-4975 a different paradigm for drug treatment
• Overcoming challenges in clinical trial design and implementation
• Clinical trial results to date in knee osteoarthritis and path forward
• Going beyond the knee
Kerrie Brady, Chief Business Officer, Centrexion Therapeutics

9.50 Introduction of a Novel, Modified Post-Operative Pain Model in Pigs
• A highly relevant and sensitive model for the assessment of novel nerve block therapeutics
• This model allows for the perineural injection of the candidate compound in volumes similar to those used in human subjects
• We will show the difference in dermal nerve density in different locations using immunohistochemistry data as well as behavioral read-outs with this model
Sigal Meilin, Chief Scientific Officer, MD Biosciences

10.30 Morning Coffee

DEEP DIVE

11.00 Elagolix for the treatment of endometriosis pain – a case study
• Replicate, double-blind randomized 6-month phase 3 trials
• Efficacy on 3 main types of endometriosis-associated pain
• Use of daily pain impact diaries
Keith Gordon, Senior Scientific Director, AbbVie

11.40 Demonstrating pharmacodynamic effects of new analgesic compounds early in clinical drug development
Dr. Geert Jan Groeneveld, Chief Scientific Officer / Chief Medical Officer, CHDR

12.20 Networking Lunch

13.20 Discovery of EP4 receptor and its use in the treatment of pain
• Identification of novel EP4 receptors
• EP4 receptors structure and mechanisms
• Case study: Preclinical model of EP4 receptors
• GSK726701A EP4 partial agonist
Lynn Kirkpatrick, CEO, Ensyce Biosciences Inc.

ELI LILLY SPOTLIGHT SESSION

14.00 Delivering new therapies to patients for the treatment of migraine: The Story of the 5-HT1F Agonist Lasmiditan
• Serotonin agonists for the acute treatment of migraine
• Introduction to the 5-HT1 family of receptors, particularly 5-HT1F receptor
• Preclinical data characterizing selective 5-HT1F agonists and presently available therapies
• Clinical data summarizing the efficacy of Lasmiditan
Kirk W. Johnson, Research Fellow, Eli Lilly and Company

14.40 Delivering new therapies to patients for the treatment of migraine: The Story of CGRP
• The timeline of key events linking CGRP to migraine
• The development of small versus large molecule inhibitors
• Broader learnings and implications for other therapies in development for migraine
Lisa Broad, Senior Director, Pain Discovery, Eli Lilly and Company

15.20 Afternoon Tea

DEVELOPING NEW PRODUCTS AND A REVIEW OF THE PAIN THERAPEUTICS SPACE - PART 2

15.50 Finally launch - now what?
• The importance of the SmPC
• Who pays for what?
• Education
Karin Hygge Blakeman, Head of Medical Affairs Nordics, Grünenthal Nordics

16.30 Panel Discussion: Translational and transitional challenges in new analgesic drug development
• The shift in translational pain research
• Overcoming the challenges in translational medicine
• Bridging the gap between development stages
Panel Moderator:
Kerrie Brady, Chief Business Officer, Centrexion Therapeutics
Panel Participants:
Dalma Sugár, Global Medical Affairs Director, Reckitt Benckiser
Kirk W. Johnson, Research Fellow, Eli Lilly and Company

17.10 Chair's closing remarks and close of day one
Workshop Overview

This workshop will review the status and development goals for more than 100 novel analgesic compounds in pre-IND through Phase 3 clinical development. Given the current Opioid Crisis in the United States, there is considerable interest in moving non-opioid and safer opioids into and through clinical development as quickly as possible without sacrificing safety or quality. There will be an open opportunity to share experiences and suggestions for ways to accomplish this by repurposing abandoned assets that already have prior clinical experience, using biomarkers and pilot studies to identify new compounds that may reveal novel mechanisms of action, and using a “nested clinical design” technique to reduce the time to achieving Proof of Efficacy in early clinical trials.

About the workshop leader

William K. Schmidt, President, NorthStar Consulting, LLC

Dr. Schmidt has more than 30 years of experience in pain medicine pharmaceutical development. He is President of NorthStar Consulting, LLC, which specializes in providing advice on preclinical and clinical studies of novel analgesic drugs to pharma and biotech companies worldwide, and simultaneously part-time VP of Clinical Development for ViroMed Co., Ltd. (Seoul, South Korea). In previous assignments, Dr. Schmidt was a key member of teams leading to the development and regulatory approval of Entereg® (alvimopan), a peripherally-acting opioid antagonist, Acelex® (polmacoxib), a dual-acting COX-2 and carbonic anhydrase inhibitor, nalbuphine (Nubain®), naltrexone (ReVia®) and the oxycodone-ibuprofen formulation used in Combutrex™. Dr. Schmidt received his Ph.D. in Pharmacology from the University of California, San Francisco.

Agenda

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<td>Registration &amp; Morning Coffee</td>
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<td>9.00</td>
<td>Opening remarks and introductions</td>
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<tr>
<td>9.10</td>
<td>Session 1 – Understanding the current opioid landscape</td>
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<td>• Current pipeline and research in opioid antagonist drugs</td>
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<td>• An overview of recent innovations in novel targets</td>
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<td>• Evaluating the regulatory landscape</td>
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<td>Session 2 – Reviewing the development goals of novel analgesics</td>
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<td>• Pre-IND – Phase 3 clinical development</td>
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<td>• Discontinued compounds – key takeaways</td>
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<td>Session 3 – Identifying novel mechanisms of actions – case studies</td>
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<td>• The use of biomarkers</td>
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<td>• Pilot studies</td>
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<td>• Nested clinical design techniques</td>
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<td>11.40</td>
<td>Session 4 – Future outlook – Group Discussion</td>
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<td>• Review of the potential opioid replacement therapies and non-opioid solutions</td>
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<td>• What can we do to accelerate development?</td>
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<td>• Moving forward, how can we address the crisis?</td>
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<td>12.20</td>
<td>Closing Remarks</td>
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<td>12.30</td>
<td>End of Workshop</td>
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