Pain Management Summit

An Evolving Industry: Abuse-Resistant Technologies, Cannabinoids, and Other Novel Alternatives to Pain Management

ATTENDEE BENEFITS

- Network and learn with pain management professionals, pharmaceutical developers, healthcare providers, and other stakeholders
- Hear about the most novel analgesics in development
- Understand how abuse-resistant technologies are evolving beyond opioids and being used for stimulants and other new chemical entities
- Understand how cannabinoids are improving the quality of pain treatment
- Identify the issues and miscommunication between care providers and guidelines when addressing complex pain scenarios
- Harness industry best practices to attract payers and maximize market access

FEATURED SPEAKERS

Caroline Arout, Ph.D.
Research Scientist and Assistant Professor of Clinical Neurobiology
NEW YORK STATE PSYCHIATRIC INSTITUTE AT COLUMBIA UNIVERSITY IRVING MEDICAL CENTER

Danielle Friend, Ph.D.
Director, Science and Regulatory Affairs
BIOTECHNOLOGY INNOVATION ORGANIZATION

Tim Pera
President and Finance Director
BRIDGE THERAPEUTICS

Robert Raffa, Ph.D.
Chief Scientific Officer
NEUMENTUM, INC.

Scott L. Dax, Ph.D.
Chief Scientific Officer
CERSCI THERAPEUTICS, INC.

Jeffrey Fudin, Pharm.D.
Chief Executive Officer and Chief Medical Officer
REMITIGATE, LLC

Joseph V. Pergolizzi, M.D.
Senior Partner
NAPLES ANESTHESIA AND PAIN ASSOCIATES

Debra R. Wilson, Ph.D.
Associate Professor
AUSTIN PEAY STATE UNIVERSITY
Contributing Faculty
WALDEN UNIVERSITY

To Register, Call 201 871 0474 or Click Here
DEAR COLLEAGUE,

As the opioid crisis continues, the need for effective pain relief remains while the risk of addiction is still a major threat. While market access struggles have proved to be a challenge for abuse-deterrent formulations, the industry has been hesitant to move forward with innovation in this area. To find a solution, the opportunities and values within the space need to be reevaluated.

ExL’s Pain Management Summit, created based off the former annual Human Abuse Liability Summit, will serve as a platform for professionals in the pain industry to discuss the latest trends in analgesic developments, including the newest progress in abuse-resistant technologies, cannabinoids and marijuana for pain management and treatment of abuse disorders, non-opioid pain drugs, and other therapeutics. It will also explore other issues contributing to the ongoing opioid crisis, including opioid guideline myths, inappropriate treatment approaches, and the transition from oxycodone overdoses to fentanyl and heroin overdoses.

Participants will leave with the latest insight on the direction the pharmaceutical pain industry is moving in, a new network of professional relationships, and the resources to move forward with novel pain therapeutics.

Sincerely,
Alyssa Smail
Associate Conference Producer
ExL Events, a division of Questex

VENUE INFORMATION
Inn at Penn, A Hilton Hotel
3600 Sandom Street
Philadelphia, PA 19104

To make reservations, please call (215) 823-6240 and request the negotiated rate for ExL’s November Meeting. You may also make reservations online using the following weblink: http://bit.ly/32rcwOC. The group rate is available until October 28, 2019. Please book your room early, as rooms available at this rate are limited.

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WHO SHOULD ATTEND
This conference is designed for representatives from pharmaceutical, medical device, and biotechnology companies with responsibilities in the following areas:

- Pain / Pain Medicine / Pain Management
- Abuse / Deterrent / Deterrence / Resistant / Resistance /
- Addiction / Addiction Treatment / Addiction Medicine
- Cannabis / Cannabinoid
- Drug Safety
- Risk Management / REMS
- Toxicology
- Behavioral Psychiatry / Behavioral Health
- Pharmaceutical Development
- Clinical Development / Operations / Affairs / Programs
- Policy
- Scientific Affairs / Medical Affairs
- Legal Affairs / Legal Counsel
- Market Access

This conference is also of interest to:

- Abuse Liability Service Providers
- CROs
- Drug Abuse Registry / Surveillance Specialists
- Formulation Service Providers
- Intellectual Property Service Providers
- Law firms
- Marketing
- Pharmacology / Clinical Pharmacology / Safety Pharmacology
- Pharmacovigilance
- Pharmacy
- Analytical Development
- Anesthesiology
- Neurobiology / Neurology
- CNS / Neuroscience
- Commercial Affairs
- Managed Care / Palliative Care
- Pharmacoeconomics / Health Economics / Outcomes Research / HEOR
- Education
- Informatics
- Quality
- R&D
- Epidemiology / Pharmacoepidemiology
- Pharmacokinetics Service Providers
- Regulatory Specialists
- REMS / Pharmacovigilance Specialists
- Toxicology Specialists
- University Professors researching pain / Addiction / Cannabinoids

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NEED TO KNOW

CBD AND THC: WHAT HEALTHCARE PROFESSIONALS NEED TO KNOW

There are numerous bioactive components in the marijuana plant. This session will provide an overview of the action of these components, modes of intake, research challenges, the state of marijuana policy, dangers, and its use for pain.

- Examine the quick movement of legalization without formalization of medicinal marijuana policy and the significant risks of chronic marijuana use
- Determine the potential the whole plant and its constituents have for multiple therapeutic purposes, including chronic pain
- Acknowledge the capabilities of CBD for the treatment of abuse disorders and addiction

12:00  LUNCH BREAK

1:00  CBD AND THC: WHAT HEALTHCARE PROFESSIONALS NEED TO KNOW

Day One

1:45  A BREAKDOWN OF CBD: PAIN TREATMENT, COMBINATION THERAPEUTICS, MYTHS, AND REGULATIONS

After the first cannabinoid-based drug was approved by the FDA for a rare epilepsy condition, a new door was opened for pharma companies. Amongst the limited amounts of research done, CBD has shown to have several beneficial effects. As a non-opioid, the cannabinoid group shows great potential in aiding in the treatment of pain while mitigating the risk of addiction.

- Exploit the myths associated with CBD
- Discuss the use of CBD in combination with other pain therapeutics
- Summarize the new CBD drug being developed for convulsive disorders and how that can lead to other pain drugs in the future

Alex Wasyli, Chief Executive Officer, NEXIEN BIOPHARMA

3:00  NETWORKING BREAK

3:45  A NOVEL NON-OPIOID THERAPEUTIC FOR THE TREATMENT OF POST-SURGICAL PAIN AND PAINFUL DIABETIC NEUROPATHY

CT-044, is a non-metal based, orally bioavailable, small molecule Reactive Species Decomposition Accelerant which destroys peroxynitrate, thereby disrupting or preventing pathways that lead to neuronal sensitization and the development of pain. In vivo, CT-044 is efficacious in pre-clinical models of acute post-incisional hyperalgesia, both prophylactically and palliatively. CT-044 is also effective in traditional irritant-induced hyperalgesic models.

CT-044 alleviates allodynia in rat models of diabetic neuropathy without central penetration, thereby avoiding CNS side effects. CT-044 has entered clinical trials and is being developed as a non-opioid therapeutic to treat and prevent post-surgical pain and to treat painful diabetic neuropathy.

- Define the need for new, improved non-opioid, therapeutics to manage different types of pain
- Explain how Reactive Species cause neuronal sensitization leading to pain
- Learn about CT-044, a Reactive Species Decomposition Accelerant (RSDAx), that destroys peroxynitrate and hydrogen peroxide, and efficacy in preclinical pain models

Scott L. Dax, Ph.D., Chief Scientific Officer, CERSCI THERAPEUTICS

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Due to bias, data taken is often manipulated and misinterpreted. Real-life scenarios often prove that guidelines provided by regulatory agencies are not always accurate for a given situation. Opioids are the only category of drugs left that still has first-generation products being used. Recent new technologies are finally allowing us to develop novel therapeutics and begin pushing the boundaries for analogics.

- Optimal pain treatment results from proper “communication” with endogenous pain and analogic physiologic mechanisms
- All commonly used analogics approaches can be improved
- Analgesics basic science and discovery has outpaced reimbursement economics

**Robert Raffa, Ph.D., Chief Scientific Officer, NEUMENTUM, INC.**

**10:00** DESMETRAMADOL: ACTIVE METABOLITE OF TRAMADOL

Tramadol, approved for moderate to moderately severe pain, is a schedule IV analogic that is less prone to abuse than schedule II opioids. Currently being used as a stop-gap solution in the opioid crisis, tramadol is now the second most prescribed analogic in the United States, with over 40 million annual prescriptions. As a prodrug, tramadol entails multiple common metabolic liabilities that adversely affect its efficacy and safety, including black box warnings.

- Compare the respiratory depression effects of typical opioids to the schedule IV analogic tramadol
- Discuss the development of desmetramadol, the new active metabolite of tramadol
- Review the results of recently published first-in-man trials that demonstrate desmetramadol to have tramadol’s analogic profile without its metabolic liabilities and drug interactions

**John A. Zebala, M.D., Ph.D., Chief Executive Officer and President, SYNTRIX PHARMACEUTICALS**

**10:45** NETWORKING BREAK

**11:15** FUNDING AN EARLY-STAGE PAIN COMPANY

A company needs more than just a great pain treatment to advance; it also needs cash. Yet, with the heyday of biotech long gone and in the face of extreme competition, how does a new company raise investment? Examine category 1 technologies and devices in the pipeline.

- Unique challenges of pain medicines
- Valuation and milestones: staging funding to limit dilution
- Funding sources and forums: who to tap and when
- Refining the message: lessons learned from 100 pitches and presentations

**Tim Pears, President and Finance Director, BRIDGE THERAPEUTICS**

**12:00** DEBUNKING MYTHS: MISINTERPRETATIONS SURROUNDING OPIOID PRESCRIBING TRENDS AND THE PSEUDOSCIENCE OF MORPHINE EQUIVALENT DOSES

Real-life scenarios often prove that guidelines provided by regulatory agencies are not always accurate for a given situation. Due to bias, data taken is often manipulated and misinterpreted. In order to find a permanent solution to the opioid crisis, we must begin to dig into the root of the issues instead of relying on political rhetoric and easy solutions to a complex problem.

- Discuss how real data has been manipulated by politicians and media and how it affects the development of novel therapeutics
- Assess the pseudoscience of morphine milligram equivalents
- Explore ways to transform the negative perception of pain drugs to a safe and necessary method of management

**Jeffrey Fudin, Pharm.D., Chief Executive Officer and Chief Medical Officer, REMITIGATE, LLC.**

**12:15** SYNTXRUM THERAPEUTICS

**12:45** LUNCH BREAK

**1:45** A MODEST PROPOSAL: ADDRESSING THE COMPONENTS AND COMPLEXITIES OF COORDINATED CARE

Within the healthcare system, there are complex medical problems like pain, depression, or even GERD that have psychological and lifestyle components with cheap, minimally monitored, simplistic solutions. Complex problems require intricate approaches that address the component parts rather than relying on finding the next “wonder drug” to address these problems.

- Learn from the experience with antidepressants, proton pump inhibitors, and opioids
- Consider the implications for setting appropriate expectations for novel therapeutics such as medical cannabis
- Discuss ways to improve incentives for healthcare organizations to encourage more personalized and specific assessment by primary care providers and others

**Steven D. Passik, Ph.D., Vice President, Scientific Affairs, Education, and Policy, COLLEGIUM PHARMACEUTICALS**

**2:00** REVISIT THE CDC GUIDELINES — LOOK WHERE WE ARE NOW!

The CDC Guidelines have been taken and used with “mission accomplished” in mind. This has been associated with forced opioid tapering, too often to zero opioids, or decreased to a maximum of 90 MME. At the same time, significant harm has occurred to chronic pain patients, who were forcibly tapered way down or even off these pain medications. Suicides have multiplied. Also, while the “Opioid Crisis” was, at least initially, about prescription opioid medications, the entire problem has morphed into a “Heroin and Fentanyl Crisis.” Finally, while the number of physicians who see chronic pain patients has sharply decreased, the physicians themselves remain under attack for the use of opioid pain medications. The political and legal aspects of the once “medical” problem are now growing and superseding the clinical aspects.

- Review past examples of the incorrect administration of opioids
- Evaluate the effects of inappropriate applications of pain medication on patients
- Investigate the reality of the Opioid Crisis, including the current issues involved and where the solutions lie

**Gary W. Jay, M.D., FAAPM, Clinical Professor, Department of Neurology, UNIVERSITY OF NORTH CAROLINA, CHAPEL HILL**

**2:30** POLICIES TO SUPPORT THE DEVELOPMENT OF NOVEL AND SAFER PAIN THERAPIES

In 2018, the Biotechnology Innovation Organization (BIO) examined the current investment trends and pipeline for pain therapies and found that compared to other therapeutic areas, investment and innovation were lacking. To promote the development of novel pain therapies moving forward, BIO developed, along with BIO member companies, policies aimed at three key areas, including 1) Supporting research to better understand the neurobiology of pain; 2) Ensuring that patients with pain are able to receive the right treatment at the right time with the proper support, without stigma; and 3) Eliminating regulatory barriers for pain treatments.

- Review investment trend data collected by BIO
- Discuss the proactive policies used to support the development of novel and safer pain therapies
- Present the progress that has been made to encourage the development of novel and safer pain therapies

**Danielle Friend, Ph.D., Director, Science and Regulatory Affairs, BIOTECHNOLOGY INNOVATION ORGANIZATION**

**4:00** CONFERENCE CONCLUDES
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**Save 25% per person when registering four**
For every three simultaneous registrations from your company, you will receive a fourth complimentary registration to the program (must register four at one time). This is a savings of 25% per person.

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Can only send three? You can still save 15% off every registration.

Offers may not be combined. Early Bird rates do not apply. To find out more about how you can take advantage of these group discounts, please call 201 871 0474

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### ONSITE PRICING

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**“Please Note: There will be an administrative charge of $300 to substitute, exchange and/or replace attendance badges with a colleague within five business days of any ExL conference.”**

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