TRAUMA THERAPEUTICS SUMMIT

Selecting the Best Drug and Device Candidates, Clinical Research Protocols, and Patient Outreach Methods to Develop Therapeutics for Acute, Chronic and Rehabilitative Care for Traumatic Injuries

April 11-12, 2016 | Wyndham Boston Beacon Hill | Boston, MA

IN-DEPTH SESSIONS:
- Analyze Breakthroughs in Regenerative Cell Therapies for Spinal Cord Injury
- Unite the Expertise of Drug Developers, Clinicians, Patient Advocates and Mental Health Practitioners
- Develop and Repurpose Drugs to Treat Post-Traumatic Stress Disorder
- Improve and Replace Flawed Animal Models for CNS Drugs
- Select Biomarkers to Stratify Traumatic Injury Patients in Clinical Trials
- Identify Optimal Clinical Endpoints for Highly Heterogeneous Patient Populations

The ONLY conference to focus on successful drug development and clinical trial management for the unmet needs of growing and heterogeneous trauma patient populations!
Dear Colleague,

Trauma is one of the largest areas of unmet need currently facing the healthcare sector, and also one of the most unpredictable. Anyone can be a victim: in any given year in America, more than two million people will be seriously injured in car accidents, and another 500,000 will require medical treatment for severe burns. As many as 9% of Americans are expected to be diagnosed with post-traumatic stress disorder at some point in their lives; nearly 300,000 military veterans already report symptoms.

I invite you to attend the Trauma Therapeutics Summit – the only event to specifically spotlight the breakthroughs in drug and research protocol development in order to better address this massive and growing public health problem.

Our expert speaking faculty offers exclusive case studies on how to:

- Improve and replace preclinical animal models for the study of traumatic injury
- Select clinical research outcomes better suited for patient populations and your drug pipeline
- Repurpose existing compounds for new CNS and trauma-related indications
- Advance drugs into crucial phase IIA pharmacodynamics trials
- Pinpoint the best candidates for PTSD drug therapies
- Collaborate with clinicians, caregivers and patient advocates to improve research outcomes
- Use biomarkers to preselect the patients most likely to respond to new therapeutics

Join us this April in Boston for the most up-to-date advances in the field of treating trauma and traumatic injury!

WHO SHOULD ATTEND?
This conference is specifically designed for pharma, biotech and med device professionals responsible for:

- Trauma/Trauma Therapeutics/Trauma Devices
- CNS/Neurology/Neuroscience/Neurobiology/Neuropsycharmacology/Pain
- Toxicology/Medical Toxicology
- Medicinal Chemistry
- R&D
- Clinical Development/Clinical Services
- Pharmacy/Pharmacology
- Emergency Medicine
- Comparative Medicine
- Consumer Healthcare
- Seating/Mobility
- Rehab/Rehabilitative/Rehabilitation/Reconstruction/Reconstructive
- Physical Medicine/PM&R
- Alliance Management
- Physician Outreach

THIS CONFERENCE IS ALSO OF INTEREST TO:

- CROs
- Labs
- Cell Therapy Specialists
- IP Law Firms
- Cold Chain Service Providers
- Urgent Care Specialists
- Human Factors Service Providers
- Point of Care Product Dispensers
- Injury Simulation Software/Imaging Companies

Wyndham Boston Beacon Hill
5 Blossom Street
Boston, MA 02114

To make reservations please call 617-742-7630 and request the negotiated rate for ExL’s April Meeting. You may also make reservations online using the following weblink: [http://bit.ly/1OfWDuP](http://bit.ly/1OfWDuP). The group rate is available until March 21, 2016. Please book your room early as rooms available at this rate are limited.

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MONDAY, APRIL 11, 2016  DAY ONE

8:00  Registration and Continental Breakfast

8:45  INTRODUCTION FROM CHAIRPERSON

BREAKTHROUGHS IN DRUG DEVELOPMENT

9:00  KEYNOTE: CELL THERAPY APPROACHES TO COMPLICATED CNS INJURIES
      TBIs and spinal injuries often have compounding secondary effects, such as inflammation and edema. Drug developers must bear this in mind when selecting both therapeutic candidates and clinical subjects.
      - Analyze different cell types and mechanisms of action that can take effect over different timeframes: acute, early chronic and late chronic
      - Understand the therapeutic impact of different time intervals between injury and drug administration
      - Review the latest advances in cell therapies and regenerative medicine
      Robert Hariri, Founder and CEO, CELGENE CELLULAR THERAPEUTICS

9:45  ANALYSIS OF OLIGODENDROCYTE REGENERATIVE CELL THERAPIES
      One possible approach to treating CNS trauma is to attempt to remyelinate axons. Interpreting preclinical and clinical results can be complicated by a wide variety of neurotropic and anti-inflammatory effects.
      - Grasp the multiple mechanisms of pathology at work in nerve trauma
      - Compare and contrast different therapeutic modalities
      - Explore potential new uses for CNS trauma therapies
      - Detail preclinical and early clinical experience with AST-OPC1 in spinal cord injuries
      Casey Case, Senior Vice President, Research and Nonclinical Development, ASTERIAS BIOTHERAPEUTICS

10:30  HYPOTHESES AND CLINICAL ENDPOINTS FOR THE TREATMENT OF POST-ACUTE TRAUMATIC BRAIN INJURY
      If nerve cells themselves are intact but their connections have been disrupted by a TBI, restimulating these pathways with dopamine weeks to months after injury may help cognitive recovery. An existing drug, apomorphine, fits this criteria, and pilot clinical studies have demonstrated good responses and suggest directions for further research.
      - Describe disorders of consciousness resulting from traumatic brain injuries
      - Explain the medical rationale and research protocol for a repurposed drug for regulatory approval to enable clinical studies
      - Prioritize outcome measures of recovery used by practitioners in the field of neuro-rehabilitation
      Neal Farber, CEO, NEUROHEALING PHARMACEUTICALS

11:15  Networking Break

11:45  REVIEW THE CURRENT USE OF PRESCRIPTION DRUGS TO TREAT PTSD
      Post-traumatic stress disorder affects about 7-8% of the US population, with a one-year prevalence of eight million adults. Moreover, 15-20% of the 2.8 million military personnel deployed to Iraq and Afghanistan have returned with PTSD. It is a very complex condition with major comorbidities, which in turn are often the targets of traditional pharmacotherapy. The effectiveness of these approaches will be reviewed in the context of a discussion of next-generation therapeutics for PTSD.
      - Survey the prescription rates and successful outcomes of repurposed antidepressants, anti-anxiety drugs and sleep drugs
      - Account for the extra challenges of substance addiction and abuse often faced by trauma survivors
      - Differentiate between the complex underlying factors causing PTSD and impacting diagnoses
      Gregory Sullivan, CMO, TONIX PHARMACEUTICALS

12:30  EXAMINE THE UNDERLYING CAUSES OF PTSD TO SELECT SUPERIOR CANDIDATES
      The challenge in developing new drug therapies for PTSD is in part tied to the multiple comorbidities frequently seen in patients. A development framework based on a unifying neurobiological hypothesis would represent a novel approach for treating PTSD. Altered vasopressin signaling has been implicated in PTSD, depression, anxiety and excessive anger/aggression. Vasopressin receptor antagonists are a new candidate class entering phase IIs that may have the potential to treat PTSD and several commonly associated disorders comprehensively. This session examines the progress in developing this class of drugs and how prior trial results might more broadly impact future designs.
      - Discuss the role of vasopressin receptors in PTSD symptoms such as hyperarousal and exaggerated response to traumatic memory
      - Examine the likelihood that disturbances in vasopressin signaling are mediating these core symptoms and comorbidities
      - Consider past clinical trial results and how they might influence your clinical trial structure and designs
      Neal Simon, CEO, AZEVAR PHARMACEUTICALS
      JoAnn Difede, Director, Program for Anxiety and Traumatic Stress Studies, WEILL CORNELL MEDICAL COLLEGE

1:15  Luncheon

2:15  ADAPT THE NEED FOR NEW PTSD THERAPEUTICS TO THE REALITIES OF THE MODERN DRUG INDUSTRY
      The pharmacy industry is faced with a desperate public need for PTSD treatments, but also remembers the troubling failure rate of other CNS drugs in clinical trials. With many large companies more likely to be institutionally risk-averse, it increasingly falls to smaller companies and biotechs to try to absorb the front-end risks of candidate development.
      - Recruit the expertise of clinical PTSD investigators, neurobiologists and military medicine specialists
      - Invite more feedback from clinicians and mental health practitioners who treat military and civilian PTSD cases
      Jim Lechleiter, Director, ASTROCYTE PHARMACEUTICALS

3:30  REALITIES OF THE MODERN DRUG INDUSTRY
      ADAPT THE NEED FOR NEW PTSD THERAPEUTICS TO THE REALITIES OF THE MODERN DRUG INDUSTRY
      THE USE OF BIOMARKERS TO AID IN THE DIAGNOSIS AND PROGNOSIS OF TBIs
      Developing a molecular taxonomy and definition of traumatic brain injury would significantly help in clinical research on drug candidates. For this approach to succeed, it is necessary to highlight current regulatory paths that take biomarkers from discovery to clinical diagnostics.
      - Evaluate biomarker applications for both acute and chronic phases of TBIs
      - Classify TBIs on a molecular level
      - Spotlight the potential for biomarker diagnostics
      Andreas Jeromin, CMO, QUANTERIX

4:15  DEVELOP DIAGNOSTIC AND PROGNOSTIC BIOMARKERS OF TRAUMATIC PATHOLOGIES TO GUIDE DRUG DEVELOPMENT
      Clinical trials will be made faster and more efficient through the use of biomarkers that can identify patients with particular TBI subtypes, and also varieties that can distinguish patients who are most likely to respond favorably to a therapy. Pharmacodynamic biomarkers will be especially helpful in proving that drugs are hitting the desired molecular targets. Since the FDA demands specific outcomes for approval, and these outcomes can be affected by so many factors unrelated to the injury, the development of these biomarkers is the only way to avoid the burden of setting up impractically large trials.
      - Develop biomarkers that correspond to specific injury mechanisms
      - Review the best candidates in current animal and early human trials
      - Pinpoint biomarker characteristics that are the most useful and applicable
      Ramon Diaz-Arrastia, Director, Clinical Research, CENTER FOR NEUROSCIENCE & REGENERATIVE MEDICINE

5:00  SELECT DRUG CANDIDATES THAT MODIFY TRAUMATIC INJURY SYMPTOMS AT LATER STAGES
      Pharma companies urgently need more phase IIa data, but this requires a clearer understanding of just what brain injury symptoms will be modified and when. Some patients may undergo further deterioration in the trauma center, and similarly, new drugs are in development to modulate the injury pathway and potentially have staggered outcomes days, months or even years later.
      - Compare enclosed head injury models to clinical data
      - Account for compounded effects of inflammation, sepsis and the cytokine storm
      - Ally with pharma and venture firms to support the best long-term candidates
      Kim Heidenreich, Professor, Pharmacology, UNIVERSITY OF COLORADO

5:45  Day One Concludes
8:00  Continental Breakfast

8:45  CHAIRPERSON’S RECAP OF DAY ONE

CLINICAL RESEARCH AND PATIENT ALLIANCE METHODS

9:00  KEYNOTE: IMPROVE AND REPLACE FLAWED ANIMAL MODELS FOR TRAUMA PATIENTS
More than 50 compounds in development for TBIs demonstrated efficacy on animal models but failed in the clinic. Many of the key symptoms are so dependent on human brain complexity that they can never be duplicated in animals, and this must be addressed as an obstacle to drug development.

- Redesign TBI drug cycles to depend less on failure-prone animal systems
- Base your studies on the human successes found by clinicians, focus groups and support groups
- Rely on animal models for proof of concept only

David Cifu, National Director, PM&R Program Office, DEPARTMENT OF VETERANS AFFAIRS

9:45  REFINE TARGET SELECTION FOR TRAUMATIC BRAIN INJURY STUDIES
Four million Americans suffer concussions every year, even in mild cases, up to 30% may continue to be symptomatic for three months. Addressing the multimodal and diffuse nature of injuries is both complex and essential for any progress.

- Map out the multiple sites for each type of injury
- Extrapolate different pathways that can cause each neurological symptom
- Adapt to the rough targeting ability of drugs for the brain
- Learn from the targeting ability of Parkinson’s drugs

Jim Lechleiter, Director, ASTROCYTE PHARMACEUTICALS

10:30  Networking Break

11:00  IMPROVE THE CONTINUUM OF CARE FOR TRAUMATIC INJURY PATIENTS
Providers of drugs and devices for injury sufferers are all too aware of the changes in rehabilitation practices in recent years. Patients are often transferred from one therapeutic setting to another in quick succession, and in many cases the teams providing therapeutics and care for patients will not interact with or even know of each other. This can have a significant impact on logistics, tracking, reimbursement and even patient recovery time.

- Analyze the varying levels and durations of care from different providers
- Target the countries and systems that still provide adequate team-based care to trauma patients
- Reconstruct a continuum-based system that allows for better outcomes

Jill Kolczynski, Director of Product Development, Powered Mobility, INVACARE

11:45  REVIEW THE PROVEN CLINICAL INTERVENTIONS FOR PTSD AND AVENUES FOR CROSS-DISCIPLINARY COOPERATION
There are three evidence-based proven interventions for PTSD but they are used on less than 10% of subjects. The expectations and practical skills of therapists and drug developers are vastly different, and there may be an avenue for pharma growth in circumstances that therapists are likely to find difficult or uninteresting.

- Identify both drugs and targeted therapeutics that work best on the amygdala and hippocampus
- Investigate the successes of CBT and EMDR therapies paired with stimulant and benzo drugs
- Shift the outcomes curve with dual therapies

Ross Zafonte, Chief, Physical Medicine and Rehabilitation, MASSACHUSETTS GENERAL HOSPITAL

12:30  Luncheon

1:30  DEPLOY A CHRONIC DISEASE MANAGEMENT MINDSET TO SELECT IDEAL THERAPEUTIC TARGETS
Since the primary neurological insult of a traumatic injury happens immediately and may be of less significance by the time the patient reaches a treatment center, it may be easier to target a secondary injury mechanism. Most current trials are targeting acute needs, but there is greater potential when examining the consequences of multiple long-term injuries.

- Discuss trial design methodologies for repeated TBIs in combat or athletic contexts
- Target the chronic mechanisms that lead to neuro-psychological problems
- Learn from the struggles of the Alzheimer’s drug field to better treat the development of chronic post-injury indications

Lee Goldstein, Director, Molecular Aging and Development Laboratory, BOSTON UNIVERSITY

2:15  PANEL: FIND THE INTERSECTION IN CRITICAL CARE DRUGS BETWEEN UNMET PATIENT NEEDS AND UNPREDICTABLE BUSINESS RETURNS

- Gauge the likely dosage recurrence and intervals for critical care drugs
- Determine the pros and cons from an investment, licensing and acquisition standpoint
- Position life or death urgent care cases appropriately in any consideration of business uncertainties
- Overcome the greatest logistic and ethical challenges in recruiting and studying patients in critical care clinical trials

Brian Windsor, CEO, LUNG THERAPEUTICS

3:15  Conference Concludes

WHAT YOUR PEERS SAY ABOUT OTHER EXL CONFERENCES ON CNS DRUG DEVELOPMENT:

“Excellent insight into neurology clinical trials; valuable information on successful development programs.”
—Medical Advisor, Global Clinical Research, LUNDBECK

“Shared very interesting topics and new ideas, rather than a rehash of presentations that we’ve heard before at the usual CNS disease conferences.”
—Head of Research, COLUCID PHARMACEUTICALS
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