Cambridge Healthtech Institute’s Third Annual

Ion Channels as Therapeutic Targets

A Flood of Potential for Drug Discovery

October 21-22, 2008 • Boston, MA

KEYNOTE SPEAKERS:

George K. Chandy, Ph.D., Professor, Physiology & BioPhysics, School of Medicine, University of California - Irvine

Michael Dabrowski, Ph.D., Head of Global Ion Channel Initiative, AstraZeneca

Laszlo Kiss, Ph.D., Senior Research Fellow, Merck Research Laboratories

SPECIAL EVENT FEATURE:

Ion Channels as Therapeutic Targets: An Industry Minireview

Peter Haddock, Ph.D., Group Leader, Ion Channel Group & CNS Biology, Pfizer

DISTINGUISHED FACULTY

Anindya Bhattacharya, Ph.D., Johnson & Johnson Pharmaceutical Research and Development LLC

Neil A. Castle, Ph.D., Icagen Inc.

George K. Chandy, M.D., Ph.D., University of California - Irvine

Mark (Mao Xiang) Chen, Ph.D., GlaxoSmithKline Research and Development

Chuan-Chu Chou, Ph.D., Schering Plough Research Institute

Michael Dabrowski, Ph.D., AstraZeneca

Gary Desir, M.D., Yale University School of Medicine

Jesus ‘Tito’ Gonzalez, Ph.D., Vertex Pharmaceuticals

Akihiko Kato, Ph.D., Eli Lilly and Company

Laszlo Kiss, Ph.D., Merck Research Laboratories

Roland Kazlawski, Ph.D., Lectus

Michael Mayer, Ph.D., University of Michigan

Dinah Misner, Ph.D., Roche Palo Alto

Birgit T. Priest, Ph.D., Merck Research Laboratories

Ken Stauderman, Ph.D., CalciMedica

Nuria Tamayo, Ph.D., Amgen

PRE-CONFERENCE SHORT COURSES:

MONDAY, OCTOBER 20

Understanding the Structural Biology of Ion Channels to Guide Drug Discovery

Heike Wulff, Ph.D., University of California - Davis

Boris S. Zhorov, Ph.D., D.Sc., McMaster University

Ion Channel Assays for Safety Screening

Gary Gintant, Ph.D., Abbott Laboratories

Laszlo Urban, M.D., Ph.D., Novartis Institutes for Biomedical Research

Harry Witchel, Ph.D., Brighton and Sussex Medical School

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PRE-CONFERENCE SHORT COURSES*  
MONDAY, OCTOBER 20

9:00am-12:00pm  
(SC2) Understanding the Structural Biology of Ion Channels to Guide Drug Discovery  
During the past decade there have been two remarkable technological breakthroughs which have transformed ion channel-based drug discovery. The first advance is using X-ray crystallography and solid-state NMR to solve the structures of ion channels, which enabled structure-guided drug design of ion-channel blockers. The other advance is the development of automated assays such as FLIPR and Ionworks which have high throughput-put screening of ion channel blocking compounds a reality. This short course is an overview on the cutting-edge development of structure-based design of ion-channel blockers. Several leading experts in the field will provide road maps to starters as well as contributing experiences of several complementary approaches.

Topics to be covered:  
• Pinpointing ion channel domains critical for specificity and activity  
• Looking at 3-D structure for selectivity and specificity  
• Oligomerization of ion channels – implications for tissue specificity  
• Designing expression systems that produce truly representative channels for screening  
Tutors: Heike Wulff, Ph.D., Assistant Professor, University of California - Davis  
Boris S. Zhvorov, Ph.D., D.Sc., Professor, Department of Biochemistry and Biomedical Sciences, McMaster University

1:30 – 2:00 Afternoon Pre-Conference Registration

2:00 – 5:00  
(SC5) Ion Channel Assays for Safety Screening  
Ion channels are involved in a complex and intricate signaling system that play an important role in affecting the cellular response to a drug and hence to the overall patient safety. For instance, the hERG potassium channel plays an important role in repolarization of cardiac myocytes and other sodium and calcium channels also control of ionic current flow in various cells. Drug-induced alterations in the translation and trafficking of the ion channel proteins and drug-induced blockade of channels resulting in reductions in ionic current are all thought be contribute to drug-related adverse events. In vitro assays using isolated cells, cell lines, and expression systems cloned for specific ion channels are now routinely used to predict the drug response. Electrophysiology experiments, using conscious or anaesthetized animals, are also conducted to identify potential drug liabilities. Over the years there have been significant improvements in both the technology and scientific understanding of how ion channels can impact drug safety. This course provides a detailed overview of the types of ion channel-based screening assays and technologies that are in use and how they are being applied to effectively monitor and predict drug safety.

Topics to be covered:  
• Overview of current and emerging assays and methodologies  
• Discussion on when and how to use these assays  
• Use of automation and high-throughput techniques  
• Comparison of platforms and applications  
• Factors affecting sensitivity and specificity  
• Emerging applications such as determining off-target adverse drug effects, looking beyond hERG channels, using action potentials as integrated test systems  
Tutors: Moderators: J. Rick Turner, Ph.D., PGCE, MICR, Chairman, Department of Clinical Research and Director, Cardiac Safety Education Center, Campbell University School of Pharmacy  
Gary Gintant, Ph.D., Senior Group Leader, Department of Integrative Pharmacology, Abbott Laboratories  
Dr Huabin Sun, Sr Research Investigator, Cardiovascular Safety Pharmacology & Discovery Toxicology, Bristol Myers Squibb Co  
Laszlo Kiss, Ph.D., Senior Research Fellow, Merck Research Laboratories  
Harry Witchel, Ph.D., Senior Lecturer in Physiology, Brighton and Sussex Medical School *separate registration required  
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Third Annual  
Ion Channels as Therapeutic Targets  
A Flood of Potential for Drug Discovery  
October 21-22

Main Conference  
TUESDAY, OCTOBER 21

7:00am – 6:30pm  
Registration Open  
7:30  
Morning Coffee  

PROGRESSING AT AN ACCELERATED PACE IN ION CHANNEL DRUG DISCOVERY

8:30  
Ion Channels as Therapeutic Targets: Minireview & Chairperson’s Remarks  
Peter Haddock, Ph.D., Group Leader, Ion Channel Group & CNS Biology, Pfizer  
This presentation will review a selected number of recent publications in the field of Ion Channel Biology and Drug Discovery. Dr. Haddock will present a synopsis of several papers in turn that have contributed to the Channel field in the last year and set the stage for the conference to follow.

KEYNOTE PRESENTATIONS:

9:00  
Ion Channels as Therapeutic Targets to Modulate Cell Proliferation  
George K. Chandy, M.D., Ph.D., Professor, Physiology & BioPhysics, School of Medicine, University of California - Irvine  
In 1984, potassium channels were discovered in lymphocytes and shown to regulate lymphocyte activation. Since then, ion channels have been described in diverse non-excitable cells and their role in regulating cell proliferation, transformation and apoptosis is better understood. Ion channels in non-excitable cells are viable therapeutic targets for many diseases. This presentation will highlight two potassium channels, Kv1.3 and KCa3.1, and the blockers we are developing as therapeutics for autoimmune diseases and atherosclerosis

9:35  
Improving Ion Channel Lead Generation Capabilities by a Multi-Disciplinary Approach  
Michael Dabrowski, Ph.D., Head of Global Ion Channel Initiative, AstraZeneca  
We identified a number of scientific and technological gaps impairing the rational pursuit of ion channels as a target class. In order to rectify this situation, identify novel solutions and enable proper ion channel lead generation we employed nine senior postdoctorates in chemistry, electrophysiology, molecular and cellular biology. The group works as a team on common themes: Chemistry, Screening Technologies, Assay Refined and Ion Channel Expression. In this talk several examples of novel solutions and technologies will be presented reflecting how the tractability of ion channels has improved.

10:10  
Grand Opening Coffee Break in the Exhibit Hall  
10:40  
Effective Screening Strategies to Expand the Pharmacology of Ion Channels and Pave the Way for the Next Generation of Ion Channel Therapeutics  
Laszlo Kiss, Ph.D., Senior Research Fellow, Merck Research Laboratories

11:10  
in-vitro and in-vivo Pharmacology of Novel TRPV1 Antagonists  
Anindya Bhattacharya, Ph.D., Senior Scientist, Pain & Related Disorders, Johnson & Johnson Pharmaceutical Research and Development LLC  
TRPV1 is a polymodal receptor that offers hope as an analgesic drug target. The objective of this presentation will be to review industrial TRPV1 drug discovery efforts including ours, discuss challenges and explore opportunities/benefits of TRPV1 intervention by small molecule antagonists. One of the key focus areas will be to discuss TRPV1 in-vitro screens used during HTS and/or lead optimization with a view of predictability/translatability of the pharmacology to in-vivo efficacy either in a pharmacodynamic or ‘diseased’ model of pathology. Some of the practical issues in a screening paradigm (species difference, recombinant versus native TRPV1, hemi-equilibrium versus equilibrium pharmacology, PK-PD and ADMET) will be presented in context of the continuum of TRPV1 drug discovery.
Progressing at an Accelerated Pace in Ion Channel Drug Discovery—Meeting the Top Two Challenges:

- Selectivity & Off-Target Effects – Using Technology to Get Past the Bottleneck
- Toward Predictive Pre-Clinical Models for Ion Channels – Translation from in vitro to in vivo

Facilitator:
Peter Haddock, Ph.D., Group Leader, Ion Channel Group & CNS Biology, Pfizer

Panelists:
Anindya Bhattacharyya, Ph.D., Senior Scientist, Pain & Related Disorders, Johnson & Johnson Pharmaceutical Research and Development LLC
George K. Chandy, M.D. Ph.D., Professor, Physiology & BioPhysics, School of Medicine, University of California - Irvine
Michael Dabrowski, Ph.D., Head of Global Ion Channel Initiative, AstraZeneca
Laszlo Kiss, Ph.D., Senior Research Fellow, Merck Research Laboratories

LEADING-EDGE PHARMACEUTICAL TARGETS

12:10pm High-Throughput Profiling of Ion Channels in Primary Human Cells
Michael Mayer, Ph.D., Department of Biomedical Engineering and Department of Chemical Engineering, University of Michigan

This talk presents a high-throughput method to quantify the functional activity of potassium ion channels in primary human lymphocytes. This method is rapid, automated, specific (here for the voltage-gated Kv1.3 ion channel), and capable of measuring, in parallel, the electrical currents of over 200 individual lymphocytes isolated from freshly drawn blood. The statistics afforded by high-throughput measurements allowed direct comparison of Kv1.3 activity in different subsets of lymphocytes, including CD4+ and CD8+ T cells, regulatory T cells, and B cells. Moreover, the results suggest that Kv1.3 ion channel activity can be used as a functional activation marker in T cells. High-throughput measurements made it possible to compare the activity of Kv1.3 channels in lymphocyte samples from multiple sclerosis (MS) patients and from rheumatoid arthritis (RA) patients with lymphocyte samples from healthy control subjects. We show that patients with progressive forms of MS have significantly increased Kv1.3 activity in peripheral T cells compared to controls. In the context of RA, preliminary data demonstrate that Kv1.3 activity may be a better biomarker for disease activity than existing markers such as C-reactive protein. We propose that profiling ion channel activity in primary human cells presents an enabling methodology that may be useful for diagnostic applications, therapeutic monitoring, drug screening, and drug safety testing.

12:45 Luncheon Technology Workshop Development and Validation of Compound Profiling Assays For Voltage-Gated Sodium Channels Using Automated Electrophysiology
Jeff Clare, Ph.D., Director, Ion Channel Group, Millipore

Voltage-gated sodium channel (Nav) inhibitors are an important class of drugs used to treat a variety of indications including arrhythmia, pain, local anaesthesia, epilepsy and bipolar disorder. Despite the indispensable role of Nav channels in mediating action potentials throughout nervous, cardiac and muscle tissues, drugs that inhibit these channels are remarkably well tolerated. This is thought to be largely due to their voltage- and use-dependent mechanism of action whereby the extent of block is greatly increased during periods of repetitive firing or sustained depolarisation as may occur, for example, during seizure activity or pain signalling. Interest in Nav channels within the pharmaceutical industry has been intensified by the discovery of human mutations in Nav1.7 that confer remarkable inability to sense pain in otherwise healthy individuals. Other subtypes have previously been implicated in pain signalling (e.g. Nav1.8 and 1.3) but, until recently, the development of subtype selective inhibitors has proved extremely challenging and the therapeutic utility of such blockers remains an important issue. This presentation will describe the development and use of a panel of robust assays for profiling the selectivity of compounds against each of the Nav subtypes, from 1.1 to 1.8. These assays use two different automated electrophysiology platforms (IonWorks and PatchXpress) and have been validated for detecting use- and voltage-dependent inhibition.

1:10 Session Break

LEADING-EDGE PHARMACEUTICAL TARGETS (CON’T)

2:20 Chairperson’s Remarks
Michael Mayer, Ph.D., Assistant Professor, Biomedical Engineering and Chemical Engineering, University of Michigan

2:25 Antagonism of the TRPV1 Channel and Thermoregulation
Nuria Tamayo, Ph.D., Principal Scientist, Amgen

The vanilloid receptor 1 (VR1, TRPV1) is a non-selective cation channel that can be activated by a variety of noxious stimuli, including capsaicin, extracellular acidity and heat. It is expressed in primary afferent neurons and is upregulated following inflammation and nerve injury. Antagonism of this channel is considered an attractive approach for the treatment of chronic pain and inflammatory hyperalgesia. We have recently advanced a TRPV1 antagonist, AMG 517, into clinical trials as a new therapy for the treatment of pain. However, in addition to the desired analgesic effects, AMG 517 significantly increased body core temperature following oral administration. Here we will discuss our two approaches to eliminate or minimize the on-target hyperthermic effect.

2:55 Discovering Small Molecule CRAC Channel Inhibitors
Ken Stauderman, Ph.D., Vice President, Research, Calcimedica
Calcimedica’s drug discovery strategy targets CRAC channels. CRAC channels are key components of the Ca2+ signaling pathway in immune cells, which is essential for adaptive immune responses. Calcimedica has acquired exclusive rights to the molecular components of CRAC channels (Orai1-3 and STIM1-2) and is using these molecules to screen for novel small molecule inhibitors for the treatment of autoimmune diseases.

3:25 Technology Watch E Unum Pluribus: One Platform, Three Programs
Arthur M. “Buzz” Brown, M.D., Ph.D., President and CEO, ChanTest Corporation

ChanTest’s 120-member ion channel library (ICL) is being validated and optimized for PatchXpress 7000A, IonWorks Quattro and FLIPRTetra (Automated Patch Clamp-Fluorescence). The single ICL-APC/FI platform supports three programs: services, supplies and drug discovery. For services, ICL “books” can be arranged for screening according to tissue (Cardiac or CNS Channel Panels), therapeutically important (Pain or Seizure Panels) or channels family (Nav 1.x, Cav x.y). For supplies, “books” are customized by instrument for purchase. For discovery, the ICL-APC/FI platform can be screened with diversity or ion channel-focused compound libraries or repurposed drug libraries. Examples of the different program applications will be presented.

3:55 Networking Refreshment Break in the Exhibit Hall

4:30 Sodium Channel Drug Discovery in the Era of Automated High-Throughput Electrophysiology
Neil A. Castle, Ph.D., Director of Biology, Senior Research Advisor, Icagen Inc.

Voltage-Gated sodium channels are excellent targets for development of drugs to treat neuroexcitatory disorders like pain and epilepsy. Identifying novel drug candidates has historically been a challenge due in part to the complex structural conformational changes that occur during Na channel gating, and the fact that many compounds only interact with specific gating states. The development of high-throughput planar patch clamp electrophysiology technologies like the PatchXpress™ and more recently the Ionworks Quattro™ have provided opportunities to effectively use automated electrophysiology in the hit and lead identification stages of sodium channel drug discovery. In this presentation we will describe how we use both of these platforms to support target and assay development, as well as screening and hit to lead progression.

5:00 Voltage-gated Sodium Channels as Targets for Pain Treatment
Dr Alexander Binshtok, Instructor in Anaesthesia, Anesthesia Clinics 309, Harvard Medical School

5:30 Panel Discussion with Speakers

6:00 Happy Hour in the Exhibit Hall

7:30 End of Day

Advisory Board
Chuan-Chu Chou, Ph.D., Fellow, Schering Plough Research Institute
Jesus “Tito” Gonzalez, Ph.D., Senior Director, Biology, Vertex Pharmaceuticals Inc.
Peter Haddock, Ph.D., Group Leader, Ion Channel Group & CNS Biology, Pfizer Inc.

Laszlo Kiss, Ph.D., Research Fellow, Neuroscience Drug Discovery, Automated Biotechnology Group, Merck Research Laboratories
Ion channel cardiac safety assays

8:30 Chairperson’s Remarks
Chuan-Chu Chou, Ph.D., Fellow, Schering Plough Research Institute

8:40 Strategies to Predict QT Prolongation and Arrhythmias: Assessing hERG and Other Cardiac Ion Channels Early in Drug Development
Dinah Misner, Associate Director, Discovery and Investigative Safety, Roche Palo Alto
Preclinical strategies to assess new chemical entities (NCEs) for cardiovascular liabilities early in the development process, with an emphasis on detection of QT prolongation and arrhythmias, will be presented. Topics to be discussed include an overview of the current regulatory guidelines around pre-clinical cardiovascular assessment, discussion of state-of-the-art technologies for in vitro testing (specifically around ion channels) and translation to in vivo results, and development of customized strategies to de-risk cardiovascular liabilities of NCEs. Additional specific examples will be provided where these new technologies have benefited projects to identify liabilities early, enabling selection of the “best” NCE moving forward.

9:10 Addressing the Challenges in Recombinant Expression for Higher Throughput Screens of Ion Channels with Cardiac Liability
Mao Xiang Chen, Ph.D., Biological and Cellular Targets, BR&AD, GlaxoSmithKline Research and Development
Ion channels of the cardiac action potential, particularly hERG, arguably carry the biggest liability in drug development. Recent years have seen the advent of a number of assay technologies which enabled higher throughput early profiling of individual cardiac ion channels. However, the data quality and throughput obtained with these platforms is critically dependent on the robustness of the expression reagent being used. The generation of high quality, recombinant cell lines and optimization of expression is therefore a key step in developing these assays and this can present significant challenges due to the diversity and organizational complexity of many channel types. This presentation focuses on several difficult to express cardiac ion channels, and demonstrates improved assays can be obtained by integration of expression and optimization strategies with planar array electrophysiology systems.

9:40 Networking Coffee Break in the Exhibit Hall

10:35 Chairperson’s Remarks
Chuan-Chu Chou, Ph.D., Fellow, Schering Plough Research Institute

10:40 Functional Modulation of AMPA Receptors by Auxiliary Subunits, TARPs
Akihiko S. Kato, Ph.D., Research Scientist, Neuroscience Discovery Research, Eli Lilly and Company
Many ion channels comprise principal and auxiliary subunits. Auxiliary subunits are effective drug targets, e.g. sulfonylureas for SUR subunit of K\textsubscript{ATP}, and gabapentin for α2δ subunit of calcium channels. We will describe TARPs (Transmembrane AMPA receptor Regulatory Proteins) auxiliary subunits of AMPA-type glutamate receptors. TARPs dramatically regulate trafficking and pharmacology of AMPA receptors. Recently, we discovered another family of TARPs, whose regulation is different from conventional TARPs. Understanding of receptor auxiliary subunits provides further dimensions for therapeutic strategies.

11:10 Inhibitors of Ion Channel Accessory Protein Interactions as Novel Therapeutics for Neuropathic and Inflammatory Pain
Loïc L’Huillier, Ph.D., Team Leader, Eletrophysiology, Lectus Therapeutics, Ltd.
Accessory proteins confer key functional properties to ion channels such as regulation of biophysical properties, and/or channel trafficking. We have identified, through the use of novel protein-protein interaction assays, series of compounds that modulate ion channel function through exploiting the interaction between (i) Kv1.1 channels and their regulatory Kvβ1 accessory protein subunits, and (ii) Cav2.2 channels and their regulatory Cavβ3 accessory protein subunits. We will present an introduction to the development and performance of robust, high-throughput Kv1.1/Kvβ1 and Cav2.2/Cavβ3 protein-protein interaction assays demonstrating the identification of novel series of ion channel modulators. We will also present subsequent functional in vitro electrophysiological characterization and in vivo evaluation of these novel ion channel modulators in models of inflammatory and neuropathic hyperalgesia.

Emerging ion channel targets for treating type II diabetes

11:40 Regulation of Glucose Metabolism by the Voltage-Gated Potassium Channel Kv1.3 and the Intracellular Calcium Sensor Synaptotagmin-7
Gary Desir, M.D., Professor, Department of Medicine, Section of Nephrology, Yale University School of Medicine
The voltage-gated potassium channel Kv1.3 plays a key role in the regulation of peripheral glucose metabolism. Channel inhibition in adipocytes leads to membrane depolarization, calcium release from intracellular stores, increased intracellular calcium, and ultimately to GLUT4 translocation to the plasma membrane. Channel deletion results in constitutive expression of GLUT4 at the plasma membrane. Knockdown of SYT-7 (synaptotagmin-7) also modulates peripheral glucose homeostasis through its action on both insulin secretion and GLUT4 traffic. Syt-7 deletion in mice leads to a diabetic state characterized by decreased insulin secretion by the pancreatic b cell, constitutive expression of GLUT4 at the plasma membrane, and decreased responsiveness to insulin in adipocytes. Since Kv1.3 regulates intracellular calcium, Syt-7 senses intracellular calcium, and are both expressed on GLUT4 vesicles, we speculate that Kv1.3 and Syt VII are components of the machinery that regulates calcium-dependent GLUT4 traffic and glucose metabolism.

12:10 Kv1.3 Channels as Targets for Genetic-Induced Obesity and Intranasal Insulin Delivery
Debra Fadool, Ph.D., Department of Biological Science, Programs in Neuroscience and Molecular Biophysics, The Florida State University
Previously, it has been demonstrated that mice with Kv1.3 gene-targeted deletion (Shaker subfamily of ion channels) fail to gain weight when placed on a high-fat diet and have increased peripheral insulin sensitivity via augmentation of GLUT4 translocation to the plasma membrane. We now show that channel deletion in a genetic model of obesity and late-onset diabetes (MC4R-null mice) reduces body weight by decreasing fat deposition and subsequent fasting leptin levels, significantly extends lifespan and increases reproductive success, and abrogates obesity by increasing locomotor activity and mass-specific metabolism. Intranasal insulin delivery (IND; inhaled insulin) to awake, wild-type mice robustly phosphorylates the channel in the olfactory bulb and increases protein-protein interactions with receptor tyrosine kinases and adaptor proteins that regulate channel biophysics. IND-treated mice had an increased short- and long-term object memory recognition, increased anxiolytic behavior, and an increased odor-discrimination using an odor habituation protocol but no change in odor threshold using a two-choice paradigm. Unlike Kv1.3 gene-targeted deletion that alters metabolism, adiposity, and axonal targeting to defined olfactory glomeruli to generate a “super-smeller” phenotype, suppression of Kv1.3 via IND had no effect on olfactory anatomy that would predict changes in odorant coding.

12:40 Close of Ion Channels Conference
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- Discovery On Target and will submit a completed one-page abstract by September 22, 2008 (Please Note: Registration must be paid in full to present poster).

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