Scientific Tracks & Abstracts
May 14, 2018

Biopharmaceutics 2018





Global Summit on

BIOPHARMA & BIOTHERAPEUTICS

May 14-15, 2018 | Montreal, Canada

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Chronic pain cured

James D Adams
University of Southern California, USA

Introduction: The Chumash Indians of California have plant medicines that cure chronic pain, including fibromyalgia, whiplash, chronic back pain and bursitis. The medicines relieve chronic pain and stop the pain from returning. However, to cure chronic pain, opioids must be stopped due to opioid induced hyperalgesia. The plant medicines are applied topically, are not addictive, do not cause tolerance and have no reported adverse reactions. California sagebrush, *ARTEMISIA CALIFORNICA*, is made into a liniment that is applied to painful areas of the skin. Black sage, Salvia *mellifera,* is made into a decoction that is used as a foot bath.

Case reports: The *S. mellifera* decoction has cured chronic pain in a fibromyalgia patient, a chronic back pain patient and a bursitis patient. The decoction can be used in conjunction with the liniment. The *A. californica* liniment has cured chronic pain in 14 chronic back pain patients, 2 bursitis patients, 4 patients with tendinitis/bursitis of the knee and one patient with tendinitis/bursitis of the hip. Conclusions: Both the decoction and the liniment contain monoterpenoids that inhibit transient receptor potential cation channels in the skin, down regulate chemokine production in the skin, relieve pain and stop chronic pain. The liniment also contains sesquiterpenes that inhibit and down regulate COX2 in the skin which relieves pain and stops chronic pain.

Speaker Biography

James D Adams received his PhD from UC San Francisco in 1981 in Pharmacology and Toxicology. His postdoctoral experience was at Baylor College of Medicine in Houston, Texas and the National Institutes of Health in Bethesda, Maryland. He served as a research assistant professor at Washington State University before coming to USC School of Pharmacy in 1987. Dr. Adams has worked on cytochrome P450 metabolism of ketamine, phencyclidine and polycyclic aromatic hydrocarbons in the laboratories of Neal Castagnoli, Anthony Trevor and Don Jerina. Under the direction of Jerry Mitchell, Dr. Adams developed a widely used assay for GSH and GSSG and showed how GSH and GSSG levels change during oxidative stress in many organs.

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Inhalable micro/nano-structured systems for macromolecular drug delivery

Sonia Al-Qadi
University of Santiago de Compostela, Spain

This work entails the development of combined micro- and nanoparticulate systems for lung delivery of therapeutic macromolecules, meeting the specific delivery requirements of the lung for efficient outcomes. The proposed micro/nanostructured systems comprised biopolymers (e.g., chitosan, hyaluronic acid), a gelling anion, a protein, and a sugar used as a drying adjuvant. The protein was nanoencapsulated in polymeric matrices, followed by microencapsulation by spray drying in the presence of the drying adjuvant, resulting in micro-scale powders with adequate aerodynamic and morphological features. Extensive physicochemical, elemental, structural and thermal investigations were pursued, with emphasis being placed on structural modifications and interactions of the protein/carrier system, at a molecular level. Afterwards, intratracheal administration of the formulations was performed in rats. Overall, studies revealed the non-invasiveness of the fabrication techniques to the macromolecule. Moreover, they confirmed the advantageous strategy of macromolecule nanoencapsulation in polymeric matrices prior to transformation into dry powders. These findings corroborated the *in vivo* data which showed a significant biological effect, as compared to the controls, highlighting the great potential of the developed systems for lung delivery of macromolecules intended for systemic or local effects.

Speaker Biography

Sonia Al-Qadi has completed her PhD in Pharmaceutical Technology from the University of Santiago de Compostela in Spain. Then, she pursued two Post-doctoral trainings in Denmark. She also worked as an Assistant Professor at the Faculties of Pharmacy in the Middle-East. Her research interests are focused on nano-drug delivery systems, biomaterials and macromolecules. She has won the Research Fellowships of Schlumberger Foundation and the Alexander von Humboldt.

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Targeting the tumor associated carbohydrate antigens

Somdutta Saha
Duke Human Vaccine Institute, USA

Tumor associated carbohydrate antigens (TACAs) are a class of glycans with important structural and signaling functions playing a major role in cell proliferation, differentiation, and apoptosis relevant to oncology. Tumor cells expressing TACAs influence prognosis and survival of cancer patients. We have used structure-based approaches to study antigen-antibody interactions in the tumor micro-environment and designed a peptidyl ligand that mimics the molecular topology of TACAs even though they are chemically dissimilar but functionally equivalent molecular structures. Our work also suggests that in designing antibodies, careful consideration should be made for somatic mutations that enhance the rigidity of an antibody. Electrostatics play a major role in the recognition of the model antigen examined. Discrimination against wanted targets through repulsive electrostatic interactions might be more fruitful than a strong optimization of target binding whereas increased specificity toward one target leads to decreased affinity toward others. Models for TACA targeting reagents are typified by TACA reactive monoclonal antibodies, lectins, and perhaps oncolytic viruses that target sialylated receptors. Peptides reactive with TACA may, in particular, be interesting carbohydrate binding agents, forming the basis of novel drugs that combine the advantages of antibodies and small molecules. We have developed a peptidyl ligand that binds to the TF or T antigen (Galβ1-3GalNAc). The designed peptidyl ligand was observed functionally to mediate cell signaling of TF expressing cell lines, suggesting that TF antigens might be functionally interesting.

Speaker Biography

Somdutta Saha has completed her PhD degree in Bioinformatics from the University of Arkansas at Little Rock in December 2013. She has investigated the developmental pathway for antibodies reactive to neo-carbohydrate antigens expressed in several metastatic cancers. She is interested in application of Bioinformatic approaches to early stage drug discovery efforts. She was also selected as the first Early Talent Post-doctoral Fellow in GlaxoSmithKline Plc., where she made significant contributions to the understanding of host-microbe interactions via metabolite signaling. Currently, she is a Staff Scientist at Duke Human Vaccines Institute in Durham, North Carolina involved in designing better immunogens for HIV patients.

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Drug target protein-protein interaction networks: A systematic perspective

Ragaee Shokralla
Ministry of Health, Kuwait

The identification and validation of drug targets are crucial in biomedical research and many studies have been conducted on analyzing drug target features for getting a better understanding on principles of their mechanisms. But most of them are based on either strong biological hypotheses or the chemical and physical properties of those targets separately. In this paper, we investigated three main ways to understand the functional biomolecules based on the topological features of drug targets. There are no significant differences between targets and common proteins in the protein-protein interactions network, indicating the drug targets are neither hub proteins which are dominant nor the bridge proteins. According to some special topological structures of the drug targets, there are significant differences between known targets and other proteins. Furthermore, the drug targets mainly belong to three typical communities based on their modularity. These topological features are helpful to understand how the drug targets work in the PPI network. Particularly, it is an alternative way to predict potential targets or extract nontargets to test a new drug target efficiently and economically. By this way, a drug target's homologue set containing 102 potential target proteins is predicted in the paper.

Speaker Biography

Ragaee Shokralla has completed his Pharm D degree at the age of 26 years from Alexandria University, Egypt. He is a clinical pharmacist at Ministry of Health - Kuwait.

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How to combine degenerative medicine with regenerative medicine using biologics and cell therapies

Michel Mikhail
BioNTech AG, Germany

The breakthrough therapies with immuno-oncology biologics aiming at stimulating the T-lymphocytes targeting the specific tumor after identification of the gene mutation pattern of the tumor using new generation sequencing (NGS), aim at stopping tumor progression in first instance then degenerating the tumor up-to complete drying-off and disappearance. After the complete degeneration of the tumor achieving a progression-free survival, the corresponding organ can be regenerated using the patient's own skin- or fat cells, to obtain induced pluripotent stem cells that regenerate the organ, this is in also relevant for visible organs like in case of breast cancer. With the stem cell therapy, deficient organs can be regenerated and human longevity significantly prolonged. Combining degenerative medicine with regenerative medicine is a vision that becomes reality.

Speaker Biography

Michel Mikhail has more than 30 years of pharmaceutical industry experience and track record of achievement in R&D and international regulatory affairs in large multinational research-based pharmaceutical as well as biotech companies. He is a Chartered Expert in Pharmacology-Toxicology, a Chartered Clinical Expert as well as a Chartered Analytical Expert. He has participated in the development of ICH guidelines, served on the Safety Working Group and Efficacy Working Group of the European Federation of Pharmaceutical Industry Associations (EFPIA) also as a Topic Leader. He has served on the Regulatory Group of the European branch of the Pharmaceutical Research and Manufacturers of America (PhRMA Europe). He is a Member of the Expert Committee of the Governmental Federal Institute of Risk Assessment (BfR) Germany and served as Member of the Expert Committee for Toxicology of the United States Pharmacopoeia (USP).

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Setting impurity specifications for biologicals

David P Elder
GlaxoSmithKline, United Kingdom

The presentation will look at the role of impurities in complex biological molecules. Typically, there are no therapeutic benefits to be derived from impurities. Therefore, all impurities should be removed or controlled to the extent possible to meet product specifications, good manufacturing practices (GMP), or other quality or safety-based criteria and drug products should contain no higher levels of residual impurities than can be supported by safety data and/or process capability. The focus will then switch to regulatory requirements for impurities that are enshrined in ICH Q3A / ICH Q3B and ICH Q6B; as well as other related impurity guidance for residual solvents (ICH Q3C), residual elemental impurities (ICH Q3D) and residual mutagenic impurities (ICH M7).

The presentation will then focus on the typical types of impurities in biological molecules before looking at an assessment of the process capability (Cpk) and impurity purging capability of the process. Then the focus will switch to allowable safety margins and the typical risk assessments that are needed to support the safety margins, before providing some concluding remarks.

Speaker Biography

Dr. Elder has 40 years of service within the pharmaceutical industry, with Sterling, Syntex and for the last 23 years with GSK. He is now an independent CMC consultant with broad based experience in formulation and analytical method development. Dr. Elder obtained his PhD in crystallography from the University of Edinburgh. Dr. Elder is a visiting professor at King's College, London. He is a Fellow of the RSC and chartered chemist and scientist. He is a member of the British Pharmacopoeia. He is the immediate past chairman of JPAG (Joint Pharmaceutical Analysis Group). He is a member of the Editorial Advisory Board for the Journal of Pharmaceutical Sciences. He has published over 131 papers in international journals and has given 17 webinars and over 138 presentations at international symposia. He has co-edited a book on the Analytical Characterization and Separation of Oligonucleotides and their Impurities and on ICH Quality Guidelines.

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Initial use of metronomic chemotherapy for stage IIIc colon cancer in 1995-1997

Michael Retsky
Harvard TH Chan School of Public Health, USA

This is a personal case report from a cancer researcher who 23 years ago chose a previously untested therapy rather than conventional adjuvant chemotherapy for recently diagnosed stage IIIc colon cancer. Metronomic chemotherapy, as this therapy is now called, is frequently discussed and is the subject of scientific investigation but has not yet been tested as researcher-patient used it those decades ago. The concern most expressed is that while it works, the mechanism is not understood. I can't explain exactly why it works but I can describe why I made the choice to use it on scientific grounds and why I would likely do something similar if diagnosed today. An important reference is Retsky, M., Swartzendruber, D., Wardwell, R., Bame, P. Computer model challenges breast cancer treatment strategy. Cancer Investigation, 12(6): 559-567, 1994. This paper was published shortly before I was diagnosed and describes my thinking at that time. It is freely available online at my DASH account at Harvard.

Speaker Biography

Michael Retsky (PhD in Physics from University of Chicago 1974) made a career change to cancer research thirty years ago. He was on Judah Folkman's staff at Harvard Medical School for 12 years. Retsky is Editor of a Springer-Nature book on breast cancer that was published in 2017 (Retsky M and Demicheli R, editors, Perioperative Inflammation as Triggering Origin of Metastasis Development). He is a founder and was for 10 years on the Board of Directors of the Colon Cancer Alliance. He has published more than 60 papers in physics and cancer. He has been Editor in Chief of two journals in cancer.

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