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6th European Biopharma Congress

September 18-19, 2018 | Amsterdam, Netherlands

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Euro Biopharma 2018

6th European Biopharma Congress

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KEYNOTE FORUM

DAY 1

Bimal Roy Krishna, Clin Pharmacol Biopharm 2018, Volume:7
DOI: 10.4172/2167-065X-C1-027

6th European Biopharma Congress

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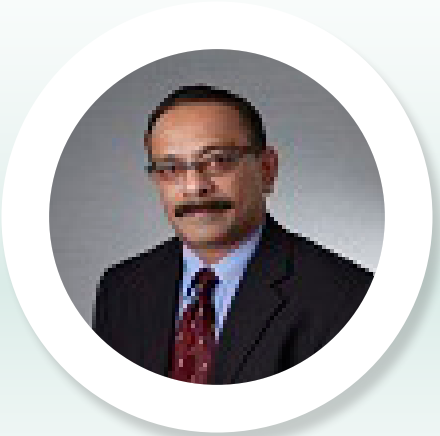

Bimal Roy Krishna
Touro University, USA

Psychotropic drugs and pregnancy

During pregnancy psychiatric disorder may occurs requiring appropriate therapy. These conditions may also be preexisting which require careful diagnosis and monitoring. While it is essential to treat such conditions, pregnancy limits the use of psychotropic drugs due to potential adverse fetal outcomes and possibly teratogenicity. Understandably improvement of the disease state may provide benefit to the developing fetus. Recent studies show that up to 20% of women suffer from mood or anxiety disorders during pregnancy. Depression and anxiety during pregnancy have been associated with a variety of adverse pregnancy outcomes. Women who suffer from psychiatric illness during pregnancy are less likely to receive adequate prenatal care and are more likely to abuse alcohol, tobacco, and other substances known to adversely affect pregnancy outcomes. IUGR, low birth weight and fetal growth retardation in children born to depressed mothers have been documented. Preterm delivery is another potential complication with an increased risk of pre-eclampsia, operative delivery, and infant admission to a special care nursery for a variety of conditions including respiratory distress, hypoglycemia, and prematurity. A number of non-pharmacological options are available including cognitive behavioral and interpersonal psychotherapy. Nevertheless a considerable percentage of patients will need pharmacological intervention keeping in mind that a number of psychotropic medications may treat more than one condition. This presentation covers maternal mental illness and pregnancy outcome and current therapeutic interventions and guidelines.

Biography

Bimal Roy Krishna is currently Professor and Director of Pharmacology at the College of Osteopathic Medicine, Touro University in Nevada. He obtained a Bachelor of Science (First Class Honors) in Pharmacology and Physiology and a Doctor of Philosophy, Medicine (OB/GYN/Pharmacology) from Monash University in Australia. He also teaches for the Step 1 USMLE and COMLEX reviews for Kaplan Medical throughout the United States and in UAE, Europe, Saudi Arabia, India, Mexico and the Caribbean. He has been teaching online for Kaplan University for over seven years. He has contributed to numerous publications and is a Member of a number of organizations including Fellow-American College of Clinical Pharmacology. His research background is in Maternal and Neonatal Pharmacology, specifically looking at materno-fetal transfer utilizing the perfused human placental and cultured syncytiotrophoblast model. Complementary and Alternative Medicine is another area of his interest.

roy.krishna@tun.touro.edu

Notes:

Oliver G Schmidt, Clin Pharmacol Biopharm 2018, Volume:7
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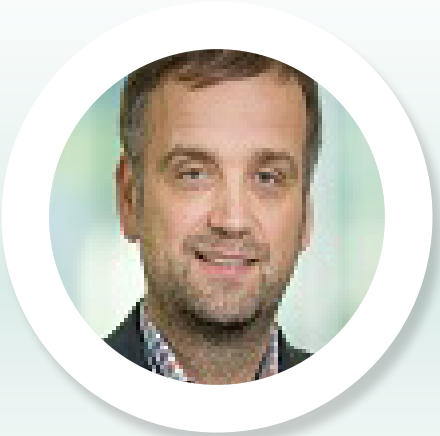
Nanomembrane microtubular devices for on- and off-chip biomedical research and development



Oliver G Schmidt

Institute for Integrative Nanosciences, Germany

Nanomembranes are thin, flexible, and transferable and can be shaped into 3D microtubular devices. This makes them attractive for a broad range of applications and scientific research fields ranging from novel hybrid heterostructure devices to ultra-compact 3D systems both on and off the chip. If nanomembranes are differentially strained they deform themselves and roll-up into microtubular structures upon release from their mother substrate. Rolled-up nanomembranes can be exploited to rigorously compact electronic circuitry into microtubular systems. As rolled-up microtubes can be easily tuned into the size range of single cells, they are perfectly suited to study single cell behaviour in sensitive yet fully integrative lab-in-a-tube systems. As off-chip components they address exciting environmental and biomedical applications. For instance, if magnetic tubes or helices are combined with spermatozoa, such biomagnetic cellular organisms offer new perspectives towards assisted reproduction technologies and drug delivery protocols. However, while such micrometer sized robots show great potential for medical applications they face equally big challenges when considering *in-vivo* operation.

Biography

Oliver G Schmidt is the Director of the Institute for Integrative Nanosciences at the Leibniz IFW Dresden, Germany. His interests bridge across several disciplines, ranging from nanomaterials and nanoelectronics to microfluidics, microrobotics and biomedical applications. He has received several awards: Otto-Hahn Medal from the Max-Planck-Society in 2000, Philip-Morris Research Award in 2002, Carus-Medal from the German Academy of Natural Scientists Leopoldina in 2005, and International Dresden Barkhausen Award in 2013. Most recently, he was awarded the Gottfried Wilhelm Leibniz-Prize 2018 of the German Research Foundation. The Leibniz-Prize is the most important research award in Germany for his outstanding work in the investigation, manufacturing and innovative application of functional nanostructures.

schmidt@ifw-dresden.de

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Debabrata (Dev) Mukhopadhyay, Clin Pharmacol Biopharm 2018, Volume:7
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Debabrata (Dev) Mukhopadhyay
Mayo Clinic College of Medicine and Science
USA

Targeting axonal guidance proteins in tumorigenesis: Role of genetic status of KRAS and TGF-1 signaling pathways

The current body of works suggests that most of the axon guidance proteins interplay with vascular system that leads to vascular development and abnormalities of those pathways usually cause several pathological consequences including cancer. The axon guidance molecules and their receptors are often incongruously expressed in cancers; however, the molecular pathways of those axon guidance proteins in the tumor cells related to tumorigenesis processes need deeper evaluation. Neuropilin-1 (NRP1), a non-tyrosine kinase receptor, originally discovered as one of the axonal guidance receptor, is overexpressed in several cancers including renal, pancreatic and lung cancers. Originally, our laboratory demonstrated that inhibition of NRP1 expression can lead to differentiation of tumor cells and growth inhibition in renal cell carcinoma and later other laboratories also demonstrated the similar observation on different tumor types including melanoma and brain tumors. Interestingly, our recent data defined a differential role of NRP1 on tumorigenesis, depends upon genetic status of KRAS in the tumor cells. More in depth signaling pathways and its intricacy with respect to drug development will be discussed in this meeting.

Biography

Debabrata Mukhopadhyay is a Professor of Biochemistry and Molecular Biology, Mayo Clinic, Rochester, MN, has a joint appointment with the Department of Physiology and Biomedical Engineering and Associate Director of Mayo Clinic Comprehensive Cancer Center for Global Alliances. He has a broad background in tumor microenvironment, with specific training and expertise in key research areas including Cancer, Cardiovascular Diseases, and Diabetes. As a Post-doctoral fellow, later as an Independent Investigator followed by as an Associate Professor at Harvard Medical School, Boston, he carried out angiogenesis and tumor microenvironment related research. After moving to Mayo Clinic as a Professor and also as Directors of both Tumor Microenvironment and Nanomedicine programs, he has been supervising additional research areas including stellate cell biology, new drug delivery systems and trained several young investigators who are now independent faculties in different institutes. Recently, he has received a Tumor Microenvironment Training Grant (T32) from National Cancer Institute. Additionally, he has initiated the biannual Mayo Clinic Angiogenesis and Tumor Microenvironment Symposium, which has been widely attended by international and national scientists and also Mayo Clinic and University of Minnesota Nanotechnology workshops. He has been serving as reviewer for several study sections in NIH, and also international funding agencies and also participating as Editorial Board Member of well received journals including *Cancer Research and Nanomedicine*.

mukhopadhyay.debabrata@mayo.edu

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Takashi Takahashi, Clin Pharmacol Biopharm 2018, Volume:7
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Takashi Takahashi
Yokohama University of Pharmacy, Japan

New synthetic technology in drug discovery

Automated synthesis and flow chemistry have attracted a great deal of attention in recent years because these processes improve both the reproducibility and reliability of synthesis. Development of automated synthetic procedures and storage of relevant digital data allow anyone to reproduce the same results anytime and anywhere using the same apparatus and reagents. As a result, synthetic chemists can spend more time on advanced and challenging problems. Automated synthesis and flow chemistry often enhance the safety profile of the synthetic processes. Flow chemistry is effective for the hazardous reactions using toxic reagents or high pressure gases. Herein, we report the automated synthesis of taxol, enediyne, lewisX and ketopiperazine analogues and the flow synthesis of peptides and aliphatic aldehydes.

Biography

Takashi Takahashi is a Professor of Medicinal Chemistry at Yokohama University of Pharmacy, Japan. He has his expertise in Natural Products and Medicinal Chemistry of drug development.

ttak@yok.hamayaku.ac.jp

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Geert C Mudde, Clin Pharmacol Biopharm 2018, Volume:7
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Geert C Mudde
OncoQR ML GmbH, Austria

Next generation immuno-therapy: tumour specific control of immune checkpoints

Using the S-TIR™ technology platform for human specific therapeutic vaccines OncoQR ML has developed two prototype vaccines for treatment of pancreatic cancer (TYG100) and breast cancer (OQR200). Vaccines derived from this platform consist of two modules, the disease specific module, "immunogen" and the generic module, "warhead", which directs the vaccines to CD32 on antigen presenting cells, especially pDCs and B cells. The immunogen in oncology is a tumour associated auto-antigen, against which under normal conditions no clinically relevant immune responses can be induced. We will present conclusive proof that it is finally possible to overcome all the tricks of cancer cells to prevent therapeutic immune responses. No more need for bulk infusion of very expensive and artificial monoclonal antibodies, which either try to mimic tumour specific B cell responses (e.g. Herceptin and Perjeta) or try to activate cytotoxic T cells that by chance may also kill tumours (e.g. Opdivo, Yervoy, Keytruda). S-TIR™ vaccines fully activate both arms of the patient's own immune system resulting in tumour specific polyclonal IgG responses simultaneously with the generation and activation of tumour specific cytotoxic T cells. The responses are reversible and boostable, thus allowing fine-tuning of the clinical responses on a patient to patient basis. S-TIR™ vaccines in contrast to the current checkpoint inhibitors do not induce autoimmune disease and are tumour specific.

Biography

Geert C Mudde has received his PhD in Immunology from the University of Utrecht in 1985 and started his international professional career at the Swiss Institute for Asthma and Allergy Research in Davos in 1989. In 1992, he joined the Pharmaceutical/Biotech Industry, where he held several Senior Management positions at the Novartis Research Institute in Vienna, Austria, the Parke Davis Research Institute in Fresnes, France, Ingenium Pharmaceuticals, Martinsried, Germany, and at Igeneon AG, Vienna, Austria. Finally, in 2006, while joining Baxter BioScience in Vienna as Interim Manager, he has Co-founded the biotech company F-star Biotechnology, where he served as "Chief Scientific Officer" from 2007 to 2009. In 2009, together with Christof Langer, he started to develop the S-TIR™ technology platform for human specific therapeutic vaccines which led to the foundation of S-TARget therapeutics GmbH in 2010. Since then he serves as CSO and Managing Director for S-TARget therapeutics as well as for the S-TIR™ technology spin-off companies OncoQR ML GmbH and TYG Oncology Ltd., which were both founded in 2013.

geert.mudde@oncoqr.com

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Heike Schoen
LUMIS International GmbH
Germany

Operational and legal challenges for biopharmaceutical and biosimilar companies conducting clinical trials in Europe

The implementation of the new ICH E6 R2 GCP guideline has created confusion, contradictory opinions about what is necessary to be implemented as sponsor oversight in clinical trials to fulfill the requirements. Sponsor oversight in general is not new, of cause, but the details to mandatory perform oversight activities and to manage compliance for all clinical trial activities have raised lots of discussions with different opinions and solutions. One important step in sponsor oversight is the selection and management of CROs and vendors. The key in CRO/vendor-selection is not only the experience with the specific indication of the CRO, however of same importance is to consider the company cultures to achieve the best alignment within the two or more parties and to define clear responsibilities and expectations. Finally when it comes to define the different involvement of the stakeholders in a clinical trial the legal aspects have to be carefully considered, not only for the sponsor-vendor relationship but also the site contracts and the different requirement of the respective countries within Europe. Another challenge for the majority of the smaller sponsors is the set-up and maintenance of clinical trial oversight management and the use of effective tools, to implement a clinical quality management system and to train clinical development department team. This suggested session should consist of three topics and three speakers include: Selection of vendors and CROs; legal aspects to conduct clinical trial in Europe; effective oversight management in clinical trials.

Biography

Heike Schoen is the Managing Director of LUMIS International GmbH, Germany. She is a Cofounder and Managing Director of LUMIS International GmbH. She has worked in leading positions in clinical research for more than 20 years. Her experience ranges from conducting national and international Phase I clinical trials all the way to registration and post marketing activities as well as business development within contract research organizations (CROs) and the biotechnology industry. Her previous positions included Operational and General Management. She holds a Master's Degree in Psychology and a Master's Degree in Business Administration.

heike.Schoen@lumisinternational.com

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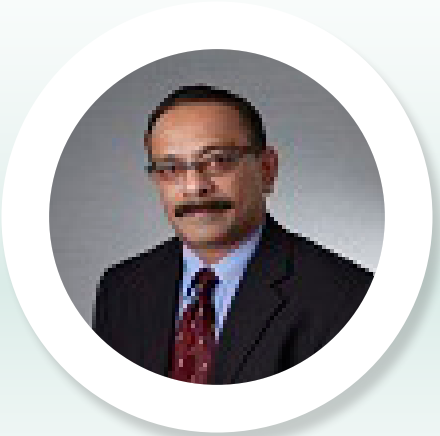

Bimal Roy Krishna
Touro University, USA

Current Clinical Indications of Immunomodulators

Immunomodulators have shown great promise in regard to prevention and treatment of various disorders ranging from autoimmune, inflammation, rheumatoid arthritis, Crohns Disease and infectious diseases. Several agents exist with different mechanisms of action, indications and side effect profiles. The two general categories are Immunosuppressive and Immunostimulatory agents. The goal has been to increase immune system specificity while minimizing toxicity peripherally and to other organs.

Infectious diseases are considered immunological disorders and neoplastic diseases are involved in an immunosuppressive state. Immunomodulators are able to stimulate natural and defensive mechanisms which are of potential clinical benefit. While they are highly beneficial, their side effects and toxicity profile can often limit their use. There are also potential drug interactions. This presentation summarizes a number of immunomodulators with their clinical indications, mechanism of action and toxicity profiles.

Biography

Bimal Roy Krishna is currently Professor and Director of Pharmacology at the College of Osteopathic Medicine, Touro University in Nevada. He obtained a Bachelor of Science (First Class Honors) in Pharmacology and Physiology and a Doctor of Philosophy, Medicine (OB/GYN/Pharmacology) from Monash University in Australia. He also teaches for the Step 1 USMLE and COMLEX reviews for Kaplan Medical throughout the United States and in UAE, Europe, Saudi Arabia, India, Mexico and the Caribbean. He has been teaching online for Kaplan University for over seven years. He has contributed to numerous publications and is a Member of a number of organizations including Fellow-American College of Clinical Pharmacology. His research background is in Maternal and Neonatal Pharmacology, specifically looking at materno-fetal transfer utilizing the perfused human placental and cultured syncytiotrophoblast model. Complementary and Alternative Medicine is another area of his interest.

roy.krishna@tun.touro.edu

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