

Euro Biopharma & Ethnopharmacology 2017



Joint Event

4th EUROPEAN BIOPHARMA CONGRESS

&

6th International Conference and Exhibition on

PHARMACOLOGY AND ETHNOPHARMACOLOGY

November 09-11, 2017 Vienna, Austria

Keynote Forum

Day 1

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Wilfried Dimpfel

University of Giessen, Germany

Reverse pharmacology of *scelletium tortuosum*

A “reverse pharmacology” approach was started with an extract of *Scelletium tortuosum*, currently sold as Zembrin® in the USA, Canada, Brazil, Malaysia, and South Africa. It is a proprietary extract of a low-alkaloid cultivated selection of *Scelletium tortuosum*, and is used by healthy people for enhancing mood, decreasing anxiety and stress and improving cognitive function under stressful situations. As test model the hippocampus slice *in vitro* was chosen to compare its effects with four of its alkaloid constituents, namely Mesembrine, Mesembrenone, Mesembrenol and Mesembranol. Measurement of the amplitude of population spikes was performed in the presence of single shock stimulation and theta burst stimulation resulting in long term potentiation (LTP). Rats were treated daily for one week with 5 or 10 mg/kg of Zembrin® before the hippocampus was taken out for *in vitro* analysis. Amplitudes of the population spikes were dose dependently attenuated. Out of four glutamate receptor agonists only Fluorowillardine was completely unable to induce its agonistic action. This points to an AMPA receptor mediated attenuation of hippocampal excitability produced by repetitive dosing of Zembrin®. Superfusing the slices directly with the alkaloids at nanomolar concentrations (3.5 – 35 nM) resulted in a concentration dependent attenuation of population spike amplitudes. However, only Mesembrenol and Mesembranol were able to prevent the action of Fluorowillardine, thus resembling the effect of the whole extract. Comparing now the chemical formula of the alkaloids in terms of a structure activity relationship, the hydroxy group at C6 instead of a carbonyl group in mesembranol seems to be essential for interaction with AMPA dependent transmission. Since attenuation of AMPA mediated transmission has been related to successful adjunctive treatment of epileptic patients, Mesembranol - following the principle and methodology of “reverse pharmacology” - might serve as chemical lead for the development of new drugs for the treatment of epilepsy.

Biography

Wilfried Dimpfel is Honorary Professor at Justus-Liebig-University Giessen, Germany, since 1983. He is Pharmacologist and got his Neurophysiological Education during 1973-1974 as Max Kade stipend (New York) at the NIH Bethesda from Phil Nelson. Together with Hans-Carlos Hofmann, a Physicist and Mathematician, he developed quantitative EEG software for research and practice. He is Consultant and CSO at NeuroCode AG, Wetzlar, Germany. He published more than 150 papers in peer-reviewed journals.

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Jamal Ouazzani

National Center for Scientific Research CNRS, Institute for Chemistry of Natural Products ICSN, France

Ethnopharmacology and neurodegenerative diseases: Past achievements and future expectations

Neurodegenerative diseases (NDs) cover various pathologies and associated disorders. The most known and disabling are Alzheimer's disease, Parkinson's disease and Huntington's disease, causing motor disorders and dementia. NDs affect the ageing population and represent one of the most challenging public health issues worldwide. The situation is particularly critical due to the increasing number of patients, the cost of treatment, and the societal impact of day-to-day care and dependence. As an example, around 7 million European citizens suffer from Alzheimer's disease with a total care cost reaching 155 billion euros each year. Besides existing drugs addressing the symptoms rather than the cause, alternative natural solutions based on natural extracts or pure compounds are driving growing interest. This presentation begins with an overview of the current state of the art in the use of natural resources and the products they contain, to combat the potential causes and consequences of NDs. We will then move on to the results we have obtained in the field, by using innovative extraction technologies and controlled biotransformation processes to enhance the effectiveness and the safety of the end products.

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Vladimir P Torchilin

Northeastern University, USA

Next generation of smart stimuli-sensitive siRNA/drug nanopreparations for cancer

Tumor therapy, especially in the case of multidrug resistant cancers, could be significantly enhanced by using siRNA down-regulating the production of proteins, which are involved in cancer cell resistance, such as Pgp or survivin. Even better response could be achieved if such siRNA could be delivered to tumors together with chemotherapeutic agent. This task is complicated by low stability of siRNA in biological surrounding. Thus, the delivery system should simultaneously protect siRNA from degradation. We have developed several types of lipid-core polymeric micelles based on PEG-phospholipid or PEI-phospholipid conjugates, which are biologically inert, demonstrate prolonged circulation in the blood and can firmly bind non-modified or reversibly-modified siRNA. Additionally, these nanopreparations can be loaded into their lipidic core with poorly water soluble chemotherapeutic agents, such as paclitaxel or camptothecin. In experiments with cancer cell monolayers, cancer cell 3D spheroids, and in animals with implanted tumors, it was shown that such co-loaded preparations can significantly down-regulate target proteins in cancer cells, enhance drug activity, and reverse multidrug resistance. In order to specifically unload such nanopreparations inside tumors, we made them sensitive to local tumor-specific stimuli, such as lowered pH, hypoxia, or overexpressed certain enzymes, such as matrix metalloproteases. Using pH-, hypoxia-, or MMP2-sensitive bonds between different components of nanopreparations co-loaded with siRNA and drugs, we were able to make the systems specifically delivering biologically active agents in tumors, which resulted in significantly improved therapeutic response.

Biography

Vladimir P Torchilin, PhD, DSc is a University Distinguished Professor of Pharmaceutical Sciences and Director, Center for Pharmaceutical Biotechnology and Nanomedicine, Northeastern University, Boston. His interests include drug delivery and targeting, nanomedicine, multifunctional and stimuli-sensitive pharmaceutical nanocarriers, biomedical polymers, experimental cancer therapy. He has published more than 400 original papers, more than 150 reviews and book chapters, wrote and edited 12 books, and holds more than 40 patents. Google Scholar shows more than 44,000 citations of his papers with H-index of 96. He is Editor-in-Chief of *Current Drug Discovery Technologies*, *Drug Delivery*, and *OpenNano*, Co-Editor of *Current Pharmaceutical Biotechnology* and on the Editorial Boards of many other journals. He received more than \$30 M from the governmental and industrial sources in research funding. He has multiple honors and awards and in 2011, Times Higher Education ranked him number 2 among top world scientists in Pharmacology for the period of 2000-2010.

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Hiroshi Ohrui

Yokohama University of Pharmacy, Japan

Development of extremely excellent anti-HIV active EFdA, focused on the design

4'-C-Ethynyl-2'-fluoro-2-deoxyadenosine (EFdA) has attracted much attention due to its extremely excellent anti-HIV properties (1. prevent the emergence of resistant HIV mutants 2. over 400 times more active than AZT and several orders of magnitude more active than the other clinical reverse-transcriptase inhibitor 2',3'-dideoxynucleoside drugs 3. very low toxic 4. long acting 5. could be used for prophylaxis, and so on). EFdA is now under clinical investigation as MK-8591 by Merck & Co. In my talk, the development of EFdA, especially the design of it will be presented and discussed. For the design of the modified nucleoside which could solve the problems (1. emergence of drug-resistant HIV-mutants. 2. adverse effects by drugs. 3. necessary to take plenty number of drugs) that the clinical drugs have, I have proposed the following working hypotheses to solve the problems. They are: (1) the way to prevent the emergence of resistant HIV mutants, (2) the way to decrease the toxicity of modified nucleosides, (3) the way to provide the nucleoside with the stability to both enzymatic and acidic hydrolysis of nucleobase. 4'-C-substituted-2'-deoxynucleoside was designed to meet the hypotheses (1), (3) and the 2-site-modification was conducted to meet the hypothesis (2). The details of the hypotheses and the reason of the 4'-C-substitution will be discussed. To prevent the deamination of adenine base, fluorine atom was introduced at the 2-position of adenine base. Finally, EFdA which is modified at the two positions of the physiologic 2'-deoxyadenosine and has extremely excellent anti-HIV properties been successfully developed.

Biography

Hiroshi Ohrui received his PhD degree (1971) from The University of Tokyo. He joined RIKEN during 1966 and moved to Tokyo University in 1981 and moved to Yokohama University of Pharmacy in 2006. He worked for Dr. J J Fox at Sloan-Kettering Institute for Cancer Research during 1972-1973 and Dr. J G Moffatt at Syntex Research during 1973-1974. He received several awards including Inoue Prize for Science (2001), Japan Prize for Agricultural Sciences (2004), The Japan Society for Analytical Chemistry Award (2004), and Japan Academy Prize (2010). His research interests cover organic synthesis, chemical biology and chiral discrimination.

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Amots Dafni

Haifa University, Israel

Rise and fall of *mandragora autumnalis* as a medicinal plant

The earlier evidences for the medicinal uses of *Mandragora autumnalis* are from Sumer and the Bible. The main uses of the mandrake (sometimes with a combination of other narcotic plants), along the generations, are: aphrodisiac, antispasmodic, sedative, anesthetic, analgesic, emetic and antidote for snakebites. For each use I'll survey: the history and the intensity throughout the history till the present day, the pharmacological background in relation to modern chemical analyses and pros and cons. It is concluded that most of the uses of *M. autumnalis*, as a medicinal plant, were almost completely abandoned. The reasons for this tendency are: 1. The poisonous and narcotic properties, as well as other uncontrolled side effects of the mandrake. 2. The development of the modern safe and efficient drugs which successfully replaced the traditional uses of the plant. The use of the mandrake as aphrodisiac still exists, maybe due to the deep belief rooted in mythology, religion and history which are hard to be eradicated.

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Roger R B Leakey

International Tree Foundation, UK

From ethnobotany to mainstream agriculture: New crops for subsistence farmers in the tropics

Statement of the Problem: Tropical agriculture is both failing local people and the environment with serious impacts on food and nutritional security, poverty, the global well-being of society and the planet. Addressing this problem requires a new mindset that recognizes the need to reverse the Cycle of Land Degradation and Social Deprivation that drives the complex processes that result in very low and declining yields of staple food crops – creating a Yield Gap.

Methodology & Theoretical Orientation: To achieve this, African smallholder farmers have requested help to diversify their farming systems with new crops that produce the traditionally and culturally-important food and medicinal products that their ancestors used to gather from forests and woodlands. Cultivating these nutritious and ecologically important species producing locally marketable products creates healthier agroecosystems and income generation opportunities; as well as new business possibilities. Over the last 25 years, techniques and strategies to allow a decentralized and participatory approach to the rapid domestication of these ethnobotanically important species have been applied and implemented in over 500 communities in Cameroon.

Findings: The results have been very positive and are being increasingly adopted and up-scaled; involving some 50 species. 1. Communities can select individual trees with desirable traits from among the 3- to 10-fold intraspecific variation available at the village-level. 2. These species are high amenable to simple, low-technology horticultural techniques for cultivar development that can be implemented at the village level. 3. Participating communities have reported numerous social and economic benefits from the domestication and cultivation of these species: and, in parallel, increased staple crop yields resulting from improved soil fertility and health.

Conclusion & Significance: There are great opportunities to develop new tropical crops producing culturally important foods and traditional medicines to transform subsistence agriculture and the lives of local people and benefit the global environment.

Biography

Roger R B Leakey DSc, FRGS has been Director of Research of a CGIAR Centre based in Kenya and responsible for research teams working in four ecological zones of Africa developing agricultural systems for subsistence farmers, and Director of Novel Crops Unit and Professor of Agroecology and Sustainable Development at James Cook University, Queensland, Australia. He has produced over 350 research publications, including two recent books on Multifunctional Agriculture. His personal research on the interface of agriculture, horticulture, forestry, ecology, food science and social sciences has focused on the domestication techniques and strategies for ethnobotanically important tree species appropriate for local implementation in rural communities. He is Vice Chair of the International Tree Foundation in UK and Co-convenor of the Agroforestry Alliance for Africa.

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Amots Dafni

Haifa University, Israel

Medicinal plants of the Bible - Past, present and future

The Holy Land is located in the cultural continuum between ancient Egypt and Mesopotamia. It is logical to assume that the main medicinal plants used were similar throughout this region. The main species were represented in the families *Solanaceae* and *Lamiaceae*. However, references to medicinal plants in the bible are uncommon and do not reflect the long-term and regular uses of these plants. While many plants mentioned in the bible have and had medicinal uses most are not mentioned within a pharmacological context within sacred verses. The main medicinal in the bible are hyssop, myrtle, myrrh, Balm of Gilead and mandrake. The first four have other ritual uses. The present day use of the plants will be surveyed to compare them to their ancient applications over the Middle East. It appears that the only plant group that has a pharmacological future, as a potential source of bioactive compounds, is the species complex known as myrrh (*Boswellia* spp.).

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Halina Baran

Karl Landsteiner Research Institute for Neurochemistry and Neuropharmacology, Austria

Lowering of kynurenic acid formation – anti-dementia drugs

Kynurenic acid (KYNA) is an endogenous metabolite of the kynurenine pathway of tryptophan degradation and is an antagonist of the glutamate ionotropic excitatory amino acid and of the nicotine cholinergic receptors and its involvement in memory impairment has been suggested. The therapeutic effect of Cerebrolysin treatment of dementia and of brain injury has been proposed because of neurotrophic properties of this compound. Since an increased kynurenine metabolism has been shown in several brain pathologies including dementia we investigated the biochemical properties of Cerebrolysin with respect to KYNA formation in an *in vitro* study. The activities of the KYNA synthesising enzymes kynurenine aminotransferase I, II and III (KAT I, KAT II, KAT III) in rat liver, and rat and human brain homogenates were analysed in the presence of Cerebrolysin. Data revealed demonstrate the ability of Cerebrolysin to lower KYNA formation in homogenates. We suggest that the anti-dementia effect of Cerebrolysin observed in Alzheimer patients could be due to Cerebrolysin induced reduction of KYNA levels, thus enhancing the cholinergic and glutamatergic neurotransmissions. D-Cycloserine, anti- mycobacterial drug, known as a partial agonist at the glycine modulatory site of the glutamatergic NMDA receptor, exerts anticonvulsive activities and improves cognitive function. We evaluated the action of D-cycloserine with respect to the biosynthetic machinery of KYNA synthesis. Interestingly, we found that D-cycloserine blockes significantly KATs activities in rat liver and brain homogenates and in the frontal cortex homogenate of human post mortem tissue, as well. These results allowed us to propose that lowering of KYNA content likely due to D- cycloserine inhibition of KATs activities might be involved in the postulated mechanism for D- cycloserine to act as a partial agonist at the glycine site of the NMDA receptor. It is reasonable to believe that this mechanism(s) is in part responsible for the improvement of symptoms like dementia, cognition and/or delusion in schizophrenia patients, Alzheimer's, HIV-1 infected patients or Parkinson's patients. Finally we evaluated the action of Jerusalem balsam with respect to the biosynthetic machinery of KYNA synthesis. Jerusalem balsam is widely used because of good reputation as a natural remedy. It is a mixture of certain plants, which supposes to have antibacterial and anti-oxidative properties. Jerusalem balsam is used to improve liver and lung diseases, as for example bronchopneumonia. Interestingly, we found that Jerusalem balsam blocks significantly KATs activities, too. Lowering of KYNA synthesis by Jerusalem balsam represents notable biochemical effect since it might influence KYNA levels. Therefore increased KYNA levels observed in stroke patient, in patient with respiration and cardiovascular problem, in neuropsychiatric disorders, in patient infected with HIV-1 and patients with bronchopneumonia could be treating by Jerusalem balsam. We speculate the possible therapeutic application and advantage of the remedy Jerusalem balsam, i.e. mixture of plants and discuss comparing to effect of anti-dementia drugs D-cycloserine and Cerebrolysin.

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Geert C Mudde

OncoQR ML GmbH, Austria

Targeted vaccination and intrinsic adjuvant function: Next generation checkpoint control of tumor specific B and T cells

OncoQR develops therapeutic cancer vaccines based on the S-TIR™ technology platform. Vaccines from this platform are (non-)human specific and able to induce strong polyclonal B cell and T cell immune responses against tumour associated (auto-)antigens. Two prototype vaccines, TYG100 and OQR200 resp., have reached *in vivo* proof of concept in non-human primates (NHP). S-TIR™ vaccines consist of 2 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 and optimally activates these cells¹. The immunogen of TYG100 is G17, a growth factor for pancreatic cancer cells² The immunogen of OQR200 targets and contains HER2/neu, overexpressed in ~20% of all breast cancer patients. TYG100 was tested as monotherapy and in combination with gemcitabine. OQR200 were tested as monotherapy and in combination with TYG100 in a cross over study. Four immunizations were given 2-3 weeks apart antibody titres were measured on a weekly basis. Under normal conditions no clinically relevant immune responses can be induced against autoantigens. However, in combination with the warhead, thanks to intrinsic check point control, all treated NHP (n=44) generated very strong and rapid dose dependent auto-antigen specific antibody (IgG and IgA) and T cell responses. Two weeks after the 2nd immunization all animals were seroconverted. Despite very high antibody titres no side effects were observed. Animals, sequentially treated with OQR200, TYG100 and OQR200 showed that the induced responses were 100% vaccine specific, resulting in animals with very high antibody titres against 2 different autoantigens at the same time. All responses are reversible and can be boosted. S-TIR™ vaccines do not induce autoimmune disease and are tumour specific while optimally mobilizing both arms of the immune system. The immune response can be fine-tuned on a patient to patient basis.

Biography

Geert C Mudde received a 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 co-founded the biotech company F-star Biotechnology. 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, and the spin-off companies OncoQR ML GmbH (2013) and TYG oncology Ltd. (2013). He serves as CSO and Managing Director for OncoQR ML.

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Kang Choon Lee

Sungkyunkwan University, South Korea

Perspective of TRAIL and PEGylated TRAIL

TNF-related apoptosis-inducing ligand (TRAIL) is a member of the TNF cytokine family capable of inducing apoptosis by its cognate receptors in cancer cells without apparent toxicity to normal cells. TRAIL has been considered as an anticancer drug due to its unique ability to selectively induce DR-mediated apoptosis in transformed cells. To date, recombinant human TRAIL and antibodies directed against TRAIL-R1 or TRAIL-R2 have been tested clinically. However, these have been disappointing, showing a very limited benefit as an antitumor agent basically due to their poor agonistic activity of these agents. And in recent years, the physiological importance of TRAIL has expanded beyond being a tumoricidal molecule to one critical for a number of clinical settings - ranging from fibrosis and autoimmunity to cardiovascular anomalies. In an attempt to overcome the poor agonistic activity and also low stability and solubility of rTRAIL *in vivo*, we developed a delivery system by using PEGylation. PEGylation of protein improves solubility, reduces the interaction with blood cells and serum proteins, provides a better biocompatibility, and extends circulation times. We recently confirmed the therapeutic efficacy of this prolonged systemic TRAIL *in vivo* on different animal models. In this talk, I will introduce how our research experience, at the crossroads of bioconjugation, drug delivery, and biology, enabled the engineering of stable TRAIL-based therapies, the discovery of clinically viable targets for cancer, inflammatory, fibrosis and autoimmune disease therapy towards clinical translation.

Biography

Kang Choon Lee is Haengdan Distinguished Professor at the SungKyunKwan University (SKKU), Korea, and was Director of the Center of Excellence for Future Pharmaceutical Education and Research in the College of Pharmacy at SKKU. He served as a Professor and Dean at the College of Pharmacy as well as the Director of the Institute of Pharmaceutical Science. Prior to joining SKKU in 1992, he was a Principal Scientist at Dong-A Pharmaceutical Co. for ten years before joining Chonnam National University as a Professor of Pharmacy. For over 30 years, his Drug Targeting Laboratory has focused on immuno-targeting including immunotoxins, preformulation and bioconjugation of peptide and protein drugs. He is internationally recognized as one of the leading experts in site-specific peptide/protein PEGylation and firstly demonstrated the therapeutic potential of novel site-specific PEGylated drugs such as GLP-1 and TRAIL. He served as President of the Korean-American Pharmaceutical Scientists Association and Vice-president of the Pharmaceutical Society of Korea and Korean Society of Pharmaceutical Science and Technology. He is a recipient of the Distinguished Pharmaceutical Scientist Award from the Pharmaceutical Society of Korea in 2002 and honored as a Fellow of the American Association of Pharmaceutical Scientists (AAPS) in 2003. He currently serves on the Editorial Advisory Board of many international scientific journals including *Pharmaceutical Research*, *Pharmaceutical Development and Technology*, *PharmSciTech*, *Journal of Drug Delivery and Heliyon*. For clinically translating and commercializing of site-specific PEGylated peptide/protein drugs developed by his laboratory, he co-founded B&L DeliPharm, Korea and Theraly Pharmaceuticals, USA.

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Anupam Bishayee

Larkin University, USA

Natural product-based cancer prevention and intervention: From ethnopharmacology to modern medicine

Natural products represent an important source for discovery and development of drugs for cancer prevention and therapy. About 80% of all drugs approved by the United States Food and Drug Administration during the last three decades for cancer therapy are either natural products per se or are based on, or mimicked natural products. Local and traditional knowledge on natural resources has been instrumental for discovery and development of numerous successful drugs. To lead the search for medicinal plants with potential anticancer activities, ethnopharmacological knowledge can provide a valuable direction. Various extracts, fractions, mixtures and pure compounds from traditionally used plants have been found to possess encouraging cytotoxic activities against numerous cancer cell lines. These agents have also been studied for cancer preventive and therapeutic properties using preclinical animal models that mimic human cancers. The cancer preventive and anticancer pharmacological attributes of various natural products and compounds can be explained by multiple cellular and molecular mechanisms, including scavenging of free radicals, detoxification of free radicals, DNA repair, alteration of cell cycles, programmed cell death (apoptosis), immune surveillance, anti-inflammatory, anti-angiogenic, anti-invasive and antimetastatic activities as well as their ability to modulate a plethora of dysregulated oncogenic signaling molecules and pathways. This presentation aims to present studies on cancer preventive and therapeutic attributes of various ethnobotanical species and underlying mechanisms of action, including those reported from our own laboratory. Current limitations and future directions of research for successful cancer drug development based on ethnobotany and ethnopharmacology will also be discussed.

Biography

Anupam Bishayee, Professor and Founding Chair, Department of Pharmaceutical Sciences, Larkin University College of Pharmacy presented an invited lecture titled "Current affairs: black currants in health and disease" during 4th International Phytocosmetics and Phytotherapy Congress held in the ancient city of Antigua, Guatemala during June 4-8, 2016. Dr. Bishayee also joined a panel of international experts on natural products during a roundtable discussion "Advances in Phytotherapy and Ethnopharmacology" which identified support mechanisms that various scientific, academic and governmental agencies should provide to raise awareness about herbal medicines and their use in the prevention and treatment of various diseases, including cancer.

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