Keynote Forum
July 05, 2019

Pharmaceutical Sciences 2019





2nd International Conference and Exhibition on

Pharmaceutics and Advanced Drug Delivery Systems

July 05-06, 2019 | Paris, France

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Hayley Lewis

Zosano Pharma Corporation, USA

A novel intracutaneous microneedle delivery system for the treatment of acute migraine

A Novel Intracutaneous Microneedle Delivery System for zolmitriptan has been developed by Zosano. This delivery system provides:

• Rapid non oral delivery and pulsatile PK profile

• Room temperature stable formulations

• Patient friendly alternative to injection

• Versatile delivery platform capable of delivering large and small molecules, and vaccines

In a recent clinical trial zolmitriptan intracutaneous microneedle delivery system was highly effective for the treatment of migraine, with statistical significance compared to placebo achieved for the two co-primary endpoints of pain freedom at 2 hours and most bothersome symptom absence at 2 hours. The results in our clinical study show the usefulness of intracutaneous microneedle delivery system for delivering zolmitriptan rapidly and yielding pharmacologic effects quickly which may be a significant advantage compared to nasal and oral formulations of zolmitriptan. In combination with our ongoing long-term safety study we believe this trial will form the basis for approval. In addition, patients have demonstrated that they are able to reliably apply the intracutaneous patches and find the product convenient and easy to use.

Speaker Biography

Hayley Lewis attained her Bachelors in Pharmaceutical Sciences from the University of Greenwich in England, and has attained several management diplomas from Kellogg School of Management, as well as Stanford's Graduate School of Business. She currently holds the position of Senior Vice President, Operations at Zosano Pharma where she oversees the functional areas of Nonclinical, R&D, Analytical Development and QC, Engineering, Manufacturing, and Regulatory Affairs. Prior to Zosano, she has spent her 26-year career in the field of Drug Delivery at Depomed, Inc, now Assertio Therapeutics, Nektar Therapeutics, Aradigm, GlaxoSmithKline, and Merck-Lipha Pharmaceuticals, involved the areas of Product Development, and Regulatory Affairs and Quality. She has published articles for Drug Development and Delivery, Pharmaceutical Technology, as well as co-authored papers published in Journal of Pharmaceutics and Journal of Pharmaceutical Sciences.

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Christophe A Serra

Ikram Ullah Khan[1,2], Nicolas Anton[1] and Thierry F Vandamme[1]

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Polymeric microcarriers for the tunable co-delivery of two incompatible APIs

This lecture proposes to study the continuous-flow production and the release properties of polymeric microcarriers whose size and morphology were controlled thanks to droplet microfluidics. Special attention will be paid to the co-delivery of two incompatible active pharmaceutical ingredients and to the tuning of the release profiles by varying operating and materials parameters.

Poly(acrylate) plain microparticles, loaded with a hydrophobic model drug (ketoprofen), were produced from an off-the-shelves capillary-based droplet generator assembled within minutes. The dispersed phase, composed of a mixture of mono- and poly-functional monomers admixed with the drug and a photoinitiator, was emulsified by a viscous aqueous solution into size-controlled droplets which were downstream polymerized on-the-fly by UV irradiations. The drug-release profile was easily tuned by varying i) the weight ratio between the two co-monomers and ii) the continuous to dispersed phase flow rate ratio. By using the aforementioned capillary-based droplet generator, poly(acrylamide) Trojan microparticles embedded with ketoprofen-loaded poly(ethyl-methyl acrylates) nanoparticles, previously obtained from the nanoemulsification of the monomer phase within an elongation flow micromixer, enable to release up to 50% of the encapsulated drug in a sustain manner.

The use of a second capillary made possible the production of 2-domain polymeric microparticles encapsulating in each domain two different and incompatible model drugs (ketoprofen and sodium fluorescein or ranitidine HCl). Thus PH-sensitive poly (methyl acrylate)-poly (acrylamide/ carboxyethyl acrylate) core-shell on one hand and Janus poly(methyl acrylate)-poly(acrylamide) microparticles on the second hand were obtained by the emulsification into droplets of two immiscible drug/monomer phases with a viscous oil phase. Then, droplets were downstream polymerized by UV irradiations at 365 nm far away from the maximum absorption wavelength of the two drugs thus ensuring their integrity. Co-release profiles were found to be function of both the morphology of the microparticles and their size and could be tuned by changing the flow rates of the two dispersed and continuous phases.

Speaker Biography

Christophe A Serra is Professor at the University of Strasbourg teaching at the European School of Chemistry, Polymers and Materials Science (ECPM). He received his MS and PhD degrees in chemical engineering from the National Engineering School of the Chemical Industries (Nancy) and Paul Sabatier University (Toulouse), respectively. His researches concern the development of intensified and integrated microfluidic-assisted polymer processes for the synthesis of architecture-controlled polymers and functional micro structured polymer particles.

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James E Trosko

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Epigenetic mechanisms in pharmacological drug discovery and toxicity studies to predict the pathogenesis of human diseases in the era of Precision Medicine and of the global metabolic disease crisis

Within global concerns of "metabolic diseases", exposures to radiations, chemicals and microbial agents, the ineffective toxicological tests, the costly animal tests, governmental restrictions on animals for drug discovery and toxicity testing, new strategies are needed to reduce and treat these acute and chronic diseases. There is no universally acceptance of the mechanisms by which radiations, chemicals and microbial agents might contribute to the pathogenesis, prevention and treatment of human diseases. Moreover, the emphasis on "Precision" or "Personalized" Medicine, together with the availability of sophisticated molecular technologies, is starting to generate tons of data, only to be analyzed by non-biologically-based algorisms. When humans are exposed to any pharmacological or toxic agent, there are only three mechanisms of responses: (a) mutagenesis by either "errors of DNA repair" or "error of DNA replication"; (b) cytotoxicity by necrosis, apoptosis, autophagy; and (c) epigenetic alteration of gene expression at the transcriptional, translational or posttranslational levels. While mutagenesis can affect human health, only UV radiation is an effective point mutagen, while ionizing radiation is a powerful chromosomal mutagen and viruses can be insertion mutagens. One needs to realize that there are three different cell types: stem cells, their progenitors and the terminally differentiated cells, each with different responses to these agents. While very controversial, it will be postulated that, even though many chemicals can induce oxidative stress, most natural and synthetic chemicals, that contribute to birth defects, cancer, cardiovascular-immunological-reproductive or neurological diseases, act as epigenetic toxicants. Those drugs and chemo preventive agents seem to act epigenetically to prevent or treat various diseases.

The current use of human adult, organ specific stem cells, grown in 3-dimension, will be shown to discover new drugs and to test for toxicities, based on their upstream epigenetic effects on either secreted- or gap junctional -intercellular communication.

Speaker Biography

James E Trosko has completed his PhD at the age of 25 from Michigan State University, USA. He is a Distinguished Emeritus Professor at Michigan State University. He spent 3 years as a postdoctoral fellow at Oak Ridge National Laboratory under Ernest Chu; Sheldon Wolff and Richard Setlow. After joining Michigan State University, he obtained an NCI- Career Development award; spent one year at the McArdle Lab for Cancer Research at the University of Wisconsin under Van R. Potter. Later he was Chief of Research at the Radiation Effects Research Foundation for two years in Hiroshima and Nagasaki, Japan. He spent 2 years at Seoul National University as a Korean "World Class University Professor". He also spent one year at the ARNAS-Civico-Regional Cancer Hospital in Palermo, Sicily. He has over 450 publications that have been cited over 17,000 times, and his publication H-index is 62.

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