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Importance of characterization of variation in the secondary endpoint measures prior to the trial: A key to a successful outcome of phase 1 trial and progression to a phase 2 stage of the study

The presentation describes importance of characterization of variation in the secondary endpoint measures prior to the trial: A key to a successful outcome of phase I trial and progression to phase 2 stage of the study based on the example of the outcomes from the recently completed phase I trial study Fenretinide (4-HPR), a master regulator of lipid metabolism controlling inflammation in patients with cystic fibrosis. The presentation describes bench to clinic development of the project and back to bench study to fully explain the mechanism of action of the drug explaining its effect on secondary end points. Dr. Radzioch laboratory has been pursuing research on cystic fibrosis lung disease for more than 15 years. Cystic fibrosis disease involves multiple organ pathology causing patients to live with many symptoms such as malabsorption of nutrients, low body mass, and malfunction of the pancreas, diabetes, infertility and osteoporosis. Aberrant regulation arachidonic acid (AA, an omega-6 fatty acid) and docosahexaenoic acid (DHA, an omega-3 fatty acid) were already known in cystic fibrosis but until now there was no treatment which could correct this problem. Dr. Radzioch laboratory demonstrated that the severe aberrations in lipid metabolism also happen during severe infections and spinal cord injury. CF mice were treated with fenretinide (4-HPR); a drug previously used in cancer trials helped the CF mice to improve their ability to fight lung infection with *Pseudomonas*.

Biography

Danuta Radzioch has been a member of "Infection and Immunity Global Health Axis and Medical Genetics and Genomics Axis within the Centre for the Translational Biology and Centre for Innovative Medicine" at the McGill University Health Centre. She brings expertise in molecular biology, host-pathogen interactions, mouse models and translational medicine. She is a Fulbright Scholar, a recipient of numerous prestigious awards, including several career awards and research grants from FRSQ, Canadian Institute of Health Research (CIHR), US Department of Defense (DoD) and the American Asthma Foundation-Sandler Program for Asthma Research (SPAR; Senior Investigator Award) and Quebec Consortium for Drug Discovery (CQDM) and Ministère de l'Enseignement supérieur, Recherche, Science et Technologie (MESRST). Following Post-doctoral training at the National Cancer Institute, NIH she has joined Faculty of Medicine at McGill in 1989 and since 2003 is a full Professor at the Department of Medicine and Human Genetics. She has held positions on review boards of several granting agencies. She is a co-founder of Laurent Pharmaceutical Inc. and serves as a Scientific Officer at the Scientific Advisory Board of Laurent Pharmaceutical Inc. She is the co-author of 169 scientific papers, 180 abstracts, several book chapters, and several patents.

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