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Relevance of non-clinical data for cell therapy development

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Abstract

Cell therapy is arguably the most complex drug development endeavor. A living organism is introduced into a patient, and a dynamic interaction between the patient's biology and the therapeutic product is initiated. It is hoped that the end result of this interaction will be a positive therapeutic effect and possibly disease modification. As with most other therapeutic interventions, prior to human trials non-clinical testing is conducted. Assessment of human cells in a non-human settingis typically more complex than the testing of small molecules, peptides or biologics. While the xenogeneic challenge of assessing product safety can be addressed using specific mouse and rat strains, models of efficacy to demonstrate proof of concept, define dosing regimens and optimal route of administration in immune compromised animals are scarce. Celgene Cellular Therapeutics is developing placental derived adherent cells (PDAC) for the treatment of inflammatory, vascular, neurological, and autoimmune diseases. Using examples from the PDAC program and other cell based products, we will discuss the utility of non-clinical and translational studies in the development of cell based therapeutics. The development of appropriate models to address both safety and efficacy questions will be described. We will provide examples of how information from safety and biodistribution studies should be used along with data from various disease models to evaluate safety, efficacy, and mechanisms of action. Integrating these activities with translational studies to design a program that supports clinical development in the most efficient manner will also be discussed.

Biography

Uri Herzberg is the Senior Director of Preclinical and Translational Development at Celgene Cellular Therapeutics, a Division of Celgene Corporation. He obtained his veterinary training at Washington State University. He left veterinary practice and completed a PhD with in neuroimmunology at the University of Minnesota, which was followed by post doctoral training at the NIH. He held positions of increased responsibilities at Cytotherapeutics, Acorda Therapeutics, Neurogen, and Johnson and Johnson where he was awarded the distinction of Excellence in Science. He is experienced with the discovery and early development of medical devices, small molecules, biologics, and cell-based therapeutics.