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Translational challenge in renal regeneration: Establishment of posology

Romaldas Maciulaitis
Lithuanian University of Health Sciences, UK

The scientific and regulatory communities are confronted during more than 10 last years with rather numerous controversial views in what is important for successful clinical translation for what is seen as promising during non-clinical studies. Not the last reason why is this still valid today is the fact that there are numerous gaps in knowledge obtained in the fundamental understanding of the biological rationale of regenerative capacities in case of various cell and gene based technologies. On the other hand, regulatory environment of this technology is heavily driven by the principles of conventional drug development and it is not necessarily easily transferable to regenerative drugs, starting from defining the effective dose. The renal regeneration could serve as one of the typical examples of this controversy. One of the biggest remaining uncertainties in cell therapy for kidney regeneration is the understanding of the mechanisms involved in the therapeutic effect. Among the possible mechanisms of action of mesenchymal stem cells (MSCs) for the treatment of acute kidney injury are the reduction of cell apoptosis and the anti-inflammatory effects via paracrine/endocrine mechanisms. The results of our studies with one of novel MSC type cells: Skeletal muscle-derived stem/progenitor cells does support alternative mode of action, that MSCs improve the functional and morphological renal recovery directly, by migrating and populating the renal cortex. This debate is not only the academic issue. The answer facilitates translation from the very beginning, enabling developer specify the potency of the product, later the dose definition, magnitude and dose response.

Biography

Romaldas Maciulaitis has completed his MD and PharmD studies more than 20 years ago and after PhD studies in Clinical Pharmacology he was involved into Drug Regulatory and Scientific Appraisals at the national (Lithuania) and international (European) levels. In 2009, he initiated new experimental Pharmacology research direction in his University in Kaunas on Regenerative Pharmacology applying cell preparations with research program focusing on PK/PD of cell therapies in renal and cartilage injuries. He has published more than 20 papers in reputed journals.

romaldasmaciulaitis@vvkt.lt

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