

A new generation of dendritic cells optimized for the use in active immunotherapy – preclinical evaluation without an animal model

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We have developed a protocol for the generation of young dendritic cells (DCs) with improved immunogenicity and optimized for the use in cell-based therapeutic vaccines. In order to analyze the safety and feasibility of this vaccine we plan to initiate a clinical trial with non-favorable acute myeloid leukemia patients. To document the safety and functionality of a new therapy, an animal model is often demanded by the regulatory authorities. However, the establishment of an animal model reflecting exactly the situation in the human setting is rarely possible. Furthermore, DC-based vaccines have been proven to be safe in more than a thousand patients, treated with various forms of DC-based vaccines over the past 15 years. Therefore, an extensive *in vitro* evaluation of the phenotype and function of our cells and a full review of published results from numerous animal studies and clinical trials in man were used for preclinical development.