Results of the Safety Evaluation of Cancer Vaccines Dealing with Novel Targets for Cancer Immunotherapy

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Abstract : Despite the many preventive and therapeutic modalities aimed at curing cancer, it remains as a serious world health problem. Promising recent developments suggest that cancer immunotherapy may be the next great hope for cancer treatment. EGFRs are receptor tyrosine kinases and it is considered an important therapeutic target related with tumor progression, and several types of molecular therapies, including monoclonal antibodies, small molecules, and vaccines, have been developed to target the HER family of receptors. On the other hand, gangliosides are membrane glycosphingolipids that contain two variants of sialic acid, the N-acetylated (NeuAc) and the N-glycolylated (NeuGc) variant. The high expression of this antigen-specific molecule has been associated with malignant tumor progression and immunosuppressive mechanisms, so ganglioside could be considered as the target for cancer immunotherapy. We have been working for several years in the safety evaluation of cancer vaccines targeting these two systems, the EGF receptor and ganglioside. We presented in this work results of repeated dose toxicity studies performed in Sprague Dawley rats and Cynomolgus monkeys, including clinical observations, body weight and rectal temperature measuring, clinical pathology analysis, gross necropsy and histological examination in rodent studies, and immunological evaluation. Immunizations were capable of inducing mainly inflammatory effects at the injection site, with findings largely attributable to the adjuvants used and probably enhanced by the immunological properties of the antigens. In general, these vaccines were shown to be well tolerated, and these studies in relevant species allow treating cancer patients with tumors during long periods with relative weight safety margin.

Keywords : cancer vaccines, safety, toxicology, rats, non human primates
Conference Title : ICT 2015 : International Conference on Toxicology
Conference Location : London, United Kingdom
Conference Dates : February 16-17, 2015