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Double-Spear 1-H2-1 Oncolytic-Immunotherapy for Refractory and Relapsing High-Risk Human Neuroblastoma and Glioma

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Abstract : Double-Spear 1-H2-1 (DS1-H2-1) is an oncolytic virus and an innovative biological drug candidate. The chemical composition of the drug product is a live attenuated West Nile virus (WNV) containing the human T cell costimulator (CD86) gene. After intratumoral injection, the virus can rapidly self-replicate in the injected site and lyse/kill the tumor by repeated infection among tumor cells. We also established xenograft tumor models in mice to evaluate the drug candidate's efficacy on those tumors. The results from preclinical studies on transplanted tumors in immunodeficient mice showed that DS1-H2-1 had significant oncolytic effects on human-origin cancers: it completely (100%) shrieked human glioma; limited human neuroblastoma growth reached as high as 95% growth inhibition rate (%TGITW). The safety data of preclinical animal experiments confirmed that DS1-H2-1 is safe as a biological drug for clinical use. In the preclinical drug efficacy experiment, virus-drug administration with different doses did not show abnormal signs and disease symptoms in more than 300 tested mice, and no side effects or death occurred through various administration routes. Intravenous administration did not cause acute infectious disease or other side effects. However, the replication capacity of the virus in tumor tissue via intravenous administration is only 1% of that of direct intratumoral administration. The direct intratumoral administration of DS1-H2-1 had a higher rate of viral replication. Therefore, choosing direct intratumoral injection can ensure both efficacy and safety.

Keywords : oncolytic virus, WNV-CD86, immunotherapy drugs, glioma, neuroblastoma
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