

Phase I, multicenter, open-label study of intravenous VCN-01 oncolytic adenovirus with or without nab-paclitaxel plus gemcitabine in patients with advanced solid tumors

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ABSTRACT

Background VCN-01 is an oncolytic adenovirus (Ad5 based) designed to replicate in cancer cells with dysfunctional RB1 pathway, express hyaluronidase to enhance virus intratumoral spread and facilitate chemotherapy and immune cells extravasation into the tumor. This phase I clinical trial was aimed to find the maximum tolerated dose/recommended phase II dose (RP2D) and dose-limiting toxicity (DLT) of the intravenous delivery of the replication-competent VCN-01 adenovirus in patients with advanced cancer.

Methods Part I: patients with advanced refractory solid tumors received one single dose of VCN-01. Parts II and III: patients with pancreatic adenocarcinoma received VCN-01 (only in cycle 1) and nab-paclitaxel plus gemcitabine (VCN-concurrent on day 1 in Part II, and 7 days before chemotherapy in Part III). Patients were required to have anti-Ad5 neutralizing antibody (NAbs) titers lower than 1/250 dilution. Pharmacokinetic and pharmacodynamic analyses were performed.

Results 26% of the patients initially screened were excluded based on high NAbs levels. Sixteen and 12 patients were enrolled in Part I and II, respectively. RP2D were 1×10^{12} viral particles (vp)/patient (Part I), and 3.3×10^{12} vp/patient (Part II). Fourteen patients were included in Part III: there were no DLTs and the RP2D was 1×10^{12} vp/patient. Observed DLTs were grade 4 aspartate aminotransferase increase in one patient (Part I, 1×10^{12} vp), grade 4 febrile neutropenia in one patient and grade 5 thrombocytopenia plus enterocolitis in another patient (Part II, 1×10^{12} vp). In patients with pancreatic adenocarcinoma overall response rate were 50% (Part II) and 50% (Part III). VCN-01 viral genomes were detected in tumor tissue in five out of six biopsies (day 8). A second viral plasmatic peak and increased hyaluronidase serum levels suggested replication after intravenous injection in all patients. Increased levels of immune biomarkers (interferon- γ , soluble lymphocyte activation

gene-3, interleukin (IL)-6, IL-10) were found after VCN-01 administration.

Conclusions Treatment with VCN-01 is feasible and has an acceptable safety. Encouraging biological and clinical activity was observed when administered in combination with nab-paclitaxel plus gemcitabine to patients with pancreatic adenocarcinoma.

Trial registration number NCT02045602.

INTRODUCTION

The use of replication-competent oncolytic viruses is a promising new option in the treatment of patients with cancer. Their mechanism of action is based on their intrinsic ability for intracellular replication in target tumor cells that leads to oncolytic activity. Regulatory agencies have so far approved two genetically engineered oncolytic viruses for clinical use via intratumoral administration. Oncorine (H101), a type 5 adenovirus approved in 2005 in China for patients with head and neck tumors,^{1,2} and T-Vec (talimogene laherparepvec), a type 1 herpes simplex approved in 2015 by the Food and Drug Administration in the USA (and later by the European Medicines Agency and the Therapeutic Goods Administration in Europe and Australia, respectively) for the treatment of advanced melanoma.³ The switch from intral-lesional to systemic delivery is challenged by limitations in systemic bioavailability and collateral damages to healthy tissues. The rapid plasmatic clearance of the viruses by liver, spleen, and macrophages⁴ limits their

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