

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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American Journal of Hospital Pharmacy, 1991

Current Medical Research and Opinion, 2006

Translating Clinical Trials to Clinical Practice, 1996

Handbook of Pharmaceutical Biotechnology Jay P Rho, Stan G Louie, 2003-04-02 This compendium of drugs produced by biotechnology covers general principles of biotechnology and pharmaceuticals Descriptions of each type of drug break down each product by pharmacology toxicities pharmacokinetics clinical applications and dosage guides There are also reviews of prescription

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Clinical Practice in Sexually Transmissible Infections Alexander McMillan, 2002 This new one stop reference source combines authoritative coverage of clinical practice in sexually transmitted diseases and sexual health with a unique and comprehensive collection of 500 superb color photographs to illustrate the key features of this worldwide problem Each chapter follows a logical format Introduction Virology Pathology Pathogenesis Epidemiology Clinical Features Complications of Infection Laboratory Diagnosis Management Prevention of Transmission and Special Circumstances Emphasizing the clinical approach to the management of the patient with a sexually transmissible infection it contains sufficient basic science to allow the reader to examine critically the rationale behind the available diagnostic tests and treatments Features colorful algorithms to facilitate discussion on patient diagnosis management and treatment Where applicable chapters include Centers for Disease Control s

guidelines Covers practical techniques of history and specimen taking in patients with suspected STD Boxed summary points of clinical guidelines management options in each chapter Addresses key areas of screening counseling and risk reduction vital to infection control Includes quality control best practice guidelines wherever possible Discusses new fundamental mechanisms of disease translated into everyday clinical practice **Hospital Physician** ,2005 Hospital Therapy ,1987-07 *Recent Advances in Clinical Oncology, Volume 1138* Frank J. Branicki,2008-11-03 The exchange of ideas and knowledge concerning cancer prevention and methods for patient education is essential to giving patients all over the world access to the most up to date therapies Cancer is the third leading cause of death in the United Arab Emirates accounting for 12% of fatalities Concerted efforts are now being made to heighten awareness with regard to prevention screening early diagnosis and multimodality therapy for advanced disease Issues addressed in this volume include evidence based oncology molecular biology diagnosis staging and treatment encompassing chemotherapy radiation therapy surgery novel experimental and therapeutic strategies and palliative care Specific topical sections relate to common disorders in the UAE such as breast hematological colorectal pediatric upper gastrointestinal gynecological and endocrine malignancy NOTE Annals volumes are available for sale as individual books or as a journal For information on institutional journal subscriptions please visit www.blackwellpublishing.com nyas ACADEMY MEMBERS Please contact the New York Academy of Sciences directly to place your order www.nyas.org Members of the New York Academy of Science receive full text access to the Annals online and discounts on print volumes Please visit www.nyas.org membership main.asp for more information about becoming a member **Resident & Staff Physician** ,1987 *Hospital Formulary* ,1992 Physicians' Desk Reference Supplements 2004 Thomson PDR,Micromedex,Physicians,2004 provides important updates between annual editions of PDR sold as a set with Supplement A publishing in July and Supplement B publishing in September Annual Meeting Proceedings American Society of Clinical Oncology. Meeting,2009 **Retina: Medical retina** Stephen J. Ryan,2001

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