

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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Alexander McMillan



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Mandell, Douglas, and Bennett's Principles and Practice of Infectious Diseases E-Book John E. Bennett, Raphael Dolin, Martin J. Blaser, Gerald L. Mandell, 2009-10-19 After thirty years PPID is still the reference of choice for comprehensive global guidance on diagnosing and treating the most challenging infectious diseases Drs Mandell Bennett and Dolin have substantially revised and meticulously updated this new edition to save you time and to ensure you have the latest clinical and scientific knowledge at your fingertips With new chapters expanded and updated coverage increased worldwide perspectives and many new contributors Mandell Douglas and Bennett s Principles and Practice of Infectious Diseases 7th Edition helps you identify and treat whatever infectious disease you see Consult this title on your favorite e reader conduct rapid searches and adjust font sizes for optimal readability Compatible with Kindle nook and other popular devices Get the answers to questions you have with more in depth coverage of epidemiology etiology pathology microbiology immunology and treatment of infectious agents than you ll find in any other infectious disease resource Find the latest diagnoses and treatments for currently recognized and newly emerging infectious diseases such as those caused by avian and swine influenza viruses Put the latest knowledge to work in your practice with new or completely revised chapters on influenza new pandemic strains new Middle East respiratory syndrome MERS virus probiotics antibiotics for resistant bacteria antifungal drugs new antivirals for hepatitis B and C Clostridium difficile treatment sepsis advances in HIV prevention and treatment viral gastroenteritis Lyme disease Helicobacter pylori malaria infections in immunocompromised hosts immunization new vaccines and new recommendations and microbiome Benefit from fresh perspectives and global insights from an expanded team of international contributors Find and grasp the information you need easily and rapidly with newly added chapter summaries These bulleted templates include diagnosis therapy and prevention and are designed as a quick summary of the chapter and to enhance relevancy in search and retrieval on Expert Consult Stay current on Expert Consult with a thorough and regularly scheduled update program that ensures access to new developments in the field advances in therapy and timely information Access the information you need easily and rapidly with new succinct chapter summaries that include diagnosis therapy and prevention Experience clinical scenarios with vivid clarity through a richly illustrated full color format that includes 1500 photographs for enhanced visual guidance

Musculoskeletal Infections, An Issue of Infectious Disease Clinics of North America Laura Certain, 2025-07-30 In this issue of Infectious Disease Clinics of North America guest editor Dr Laura Certain brings her considerable expertise to the topic of Musculoskeletal Infections Top experts present current data on how best to diagnose and manage diabetic foot infections periprosthetic joint infections vertebral osteomyelitis infection after fracture fixation and more Notably in many cases the optimal treatment approach remains unclear in those cases authors present what data is available and how experts in orthopedic infections typically proceed In addition surgical colleagues provide a brief overview of considerations for surgical management of these infections Contains

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Pulmonary Circulation Andrew J Peacock,Robert Naeije,Lewis J Rubin,2011-05-27 Authoritative comprehensive and definitive Pulmonary Circulation builds on the success of its previous two editions by providing practising respiratory physicians with a highly ordered unique reference work on the structure function and pathophysiology of the pulmonary circulation New for the third edition Thoroughly revised with comprehensive coverage from diagnosis and clinical evaluation of pulmonary hypertension to imaging techniques disorders and treatment A new truly global team of expert editors authors and key opinion leaders provide a wealth of detail on the latest developments and issues New chapters such as paediatrics critical care special environments including high altitude and underwater More quality chapters authors illustrations with thorough and thoughtful referencing make this book a contemporary essential reference text Pulmonary Circulation remains an essential resource for pulmonary hypertension specialists and should prove invaluable in all respiratory cardiac and intensive care units Pulmonary Manifestations of Systemic Diseases Wim A. Wuyts,Vincent Cottin,Paolo Spagnolo,Athol U. Wells,2019-12-01 This Monograph provides expert clinical guidance on these difficult diseases which will be helpful to both respiratory and nonrespiratory physicians alike The initial chapters consider diagnostic issues pulmonary function tests and techniques that are currently in development The book then goes on to cover a variety of pulmonary manifestations of very different disease entities such as connective tissue diseases systemic vasculitis and much more Current Medical Research and Opinion ,2006 **Textbook of Ocular Pharmacology** Thom J. Zimmerman,1997 This reference highlighting the latest breakthroughs in ocular pharmacology presents information on disease pathogenesis and pharmacological treatment of a wide range of ocular conditions *Interstitial Lung Disease* Marvin I. Schwarz,Talmadge E. King,2003 *Interstitial Lung Disease* Fourth Edition is a complete publication of interstitial lung diseases and includes clinical pathologic radiologic and physiologic evaluation of the patient with ILD It provides a basic pathobiology and a complete description of individual disease entities The book covers a wide array of disorders sarcoidosis asbestosis hypersensitivity pneumonitis drug induced lung disease connective tissue disease and pulmonary vasculitis to name but a few This new edition also features an examination of future potential therapies for interstitial lung disease *Interstitial Lung Disease* is divided into three sections The Clinical Approach section provides the basis for recognizing the key features that allow a specific diagnosis to be achieved The section dedicated to Basic Mechanisms emphasizes the many advances in genetics and cellular and molecular biology that have greatly expanded our understanding of the biological processes involved in the pathogenesis of the

interstitial lung diseases The third section titled Clinical Entities describes the clinical manifestations radiologic patterns histopathological features and management of the specific process

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

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Hospital Therapy, 1987-07 *Hospital Physician*, 2005

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

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Table of Contents A Multicenter Open Label Study Of An Intravenous Short

1. Understanding the eBook A Multicenter Open Label Study Of An Intravenous Short
 - The Rise of Digital Reading A Multicenter Open Label Study Of An Intravenous Short
 - Advantages of eBooks Over Traditional Books
2. Identifying A Multicenter Open Label Study Of An Intravenous Short
 - Exploring Different Genres
 - Considering Fiction vs. Non-Fiction
 - Determining Your Reading Goals
3. Choosing the Right eBook Platform
 - Popular eBook Platforms
 - Features to Look for in an A Multicenter Open Label Study Of An Intravenous Short
 - User-Friendly Interface
4. Exploring eBook Recommendations from A Multicenter Open Label Study Of An Intravenous Short
 - Personalized Recommendations
 - A Multicenter Open Label Study Of An Intravenous Short User Reviews and Ratings

- A Multicenter Open Label Study Of An Intravenous Short and Bestseller Lists
- 5. Accessing A Multicenter Open Label Study Of An Intravenous Short Free and Paid eBooks
 - A Multicenter Open Label Study Of An Intravenous Short Public Domain eBooks
 - A Multicenter Open Label Study Of An Intravenous Short eBook Subscription Services
 - A Multicenter Open Label Study Of An Intravenous Short Budget-Friendly Options
- 6. Navigating A Multicenter Open Label Study Of An Intravenous Short eBook Formats
 - ePub, PDF, MOBI, and More
 - A Multicenter Open Label Study Of An Intravenous Short Compatibility with Devices
 - A Multicenter Open Label Study Of An Intravenous Short Enhanced eBook Features
- 7. Enhancing Your Reading Experience
 - Adjustable Fonts and Text Sizes of A Multicenter Open Label Study Of An Intravenous Short
 - Highlighting and Note-Taking A Multicenter Open Label Study Of An Intravenous Short
 - Interactive Elements A Multicenter Open Label Study Of An Intravenous Short
- 8. Staying Engaged with A Multicenter Open Label Study Of An Intravenous Short
 - Joining Online Reading Communities
 - Participating in Virtual Book Clubs
 - Following Authors and Publishers A Multicenter Open Label Study Of An Intravenous Short
- 9. Balancing eBooks and Physical Books A Multicenter Open Label Study Of An Intravenous Short
 - Benefits of a Digital Library
 - Creating a Diverse Reading Collection A Multicenter Open Label Study Of An Intravenous Short
- 10. Overcoming Reading Challenges
 - Dealing with Digital Eye Strain
 - Minimizing Distractions
 - Managing Screen Time
- 11. Cultivating a Reading Routine A Multicenter Open Label Study Of An Intravenous Short
 - Setting Reading Goals A Multicenter Open Label Study Of An Intravenous Short
 - Carving Out Dedicated Reading Time
- 12. Sourcing Reliable Information of A Multicenter Open Label Study Of An Intravenous Short
 - Fact-Checking eBook Content of A Multicenter Open Label Study Of An Intravenous Short
 - Distinguishing Credible Sources

13. Promoting Lifelong Learning
 - Utilizing eBooks for Skill Development
 - Exploring Educational eBooks
14. Embracing eBook Trends
 - Integration of Multimedia Elements
 - Interactive and Gamified eBooks

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