UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): May 16, 2022

SYNTHETIC BIOLOGICS, INC.

(Exact name of registrant as specified in its charter)

Nevada	**001-12584**	**13-3808303**
(State or other jurisdiction of incorporation)	(Commission File No.)	(IRS Employer Identification No.)

9605 Medical Center Drive, Suite 270
Rockville, Maryland 20850
(Address of principal executive offices and zip code)

(301) 417-4364
Registrant's telephone number, including area code

N/A
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common stock, par value $0.001 per share	SYN	NYSE American LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in in Rule 405 of the Securities Act of 1933 (17 CFR §230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by checkmark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 7.01 Regulation FD Disclosure.

As previously announced by Synthetic Biologics, Inc., (the "Company"), on May 16, 2022, at an oral presentation at the 25th Annual Meeting of the American Society of Gene & Cell Therapy, Ramon Alemany, Ph.D., Head of the Immunotherapy and Virotherapy Group at the Translational Research Laboratory of the Institut Catala d'Oncologia (ICO) and Institut de Investigacio Biomedica de Bellvitage and a founding member of VCN Biosciences, S.L., presented preclinical results showcasing the potential of VCN-11 to balance safety, with no major toxicities observed, and effectively target tumors after intravenous re-administration, even in the presence of high level NAbs.

A copy of the presentation materials are attached as Exhibit 99.1 to this Report on Form 8-K.

Item 8.01 Other Information.

On May 16, 2022, Ramon Alemany, Ph.D., Head of the Immunotherapy and Virotherapy Group at the Translational Research Laboratory of the Institut Catala d'Oncologia (ICO) and Institut de Investigacio Biomedica de Bellvitage and a founding member of VCN Biosciences, presented at the 25th Annual Meeting of the American Society of Gene & Cell Therapy preclinical results showcasing the potential of VCN-11 to balance safety, with no major toxicities observed, and effectively target tumors after intravenous re-administration, even in the presence of high level NAbs.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Presentation Materials presented at the 25th Annual Meeting of the American Society of Gene & Cell Therapy
104	Cover Page Interactive Data File (embedded within the XBRL document)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Dated: May 16, 2022

SYNTHETIC BIOLOGICS, INC.

By: /s/ Steven A. Shallcross
Name: Steven A. Shallcross
Title: Chief Executive Officer
and Chief Financial Officer

Oncolytic Adenovirus With Hyaluronidase Activity That Evades Neutralizing Antibodies And Allows Re-administration: VCN-11

Ana Mato-Berciano , Maria V. Maliandi, Sara Morgado , Marti Farrera-Sal, Paz Moreno, Rafael Moreno, Luis A. Rojas, Gabriel Capellà, Miriam Bazan-Peregrino, Manel Cascallo , and

Ramon Alemany
Virotherapy Group

ICO
Institut Català d'Oncologia
Hospital Duran i Reynals

IDIBELL
Institut d'Investigació Biomèdica de Bellvitge

Disclosures

R. Alemany is advisor and owns stock of VCN Biosciences / Synthetic Biologics

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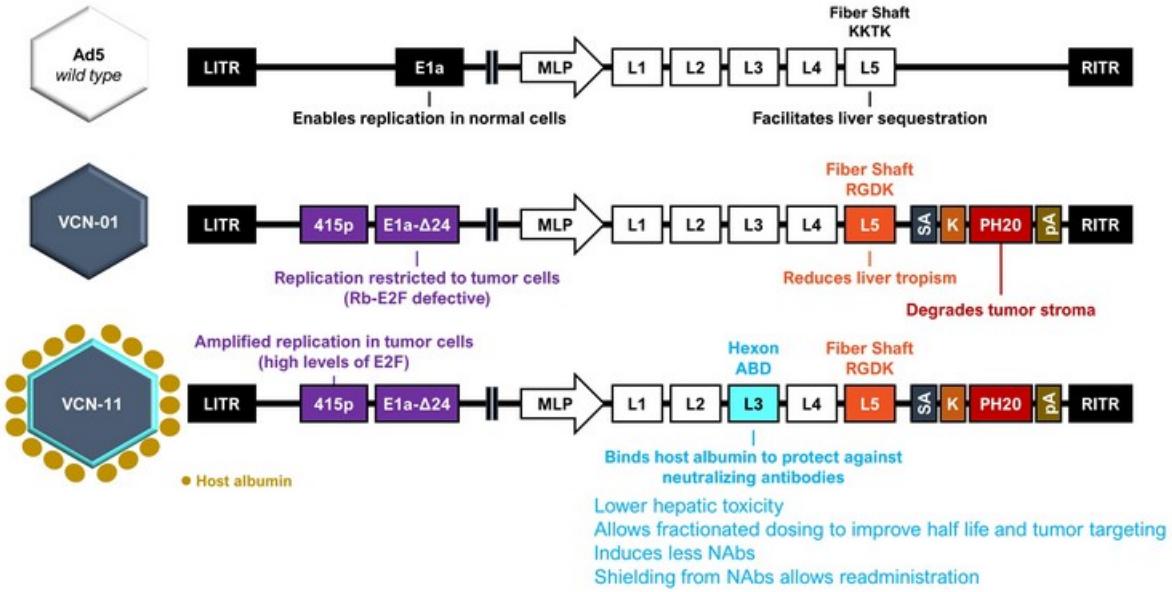
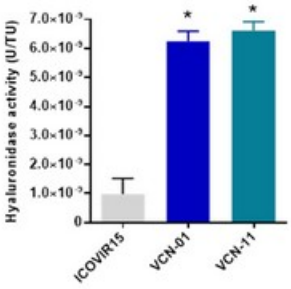
VCN-01 and VCN-11 oncolytic adenoviruses



Lower hepatic toxicity
Allows fractionated dosing to improve half life and tumor targeting
Induces less NAbs
Shielding from NAbs allows readministration

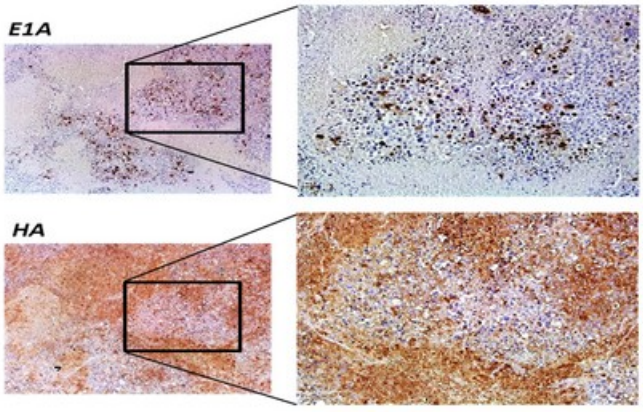
VCN-11 expresses hyaluronidase

In vitro:

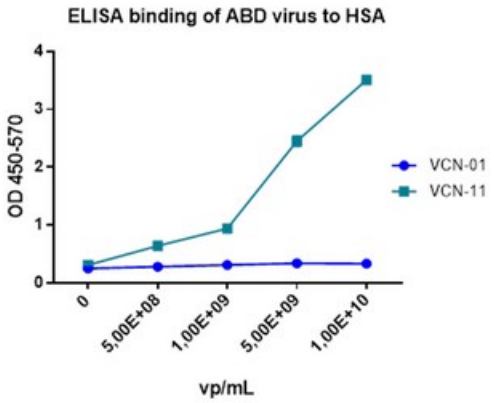


In vivo: VCN-11 Infection causes hyaluronan degradation

Melanoma
SKmel28 tumors
IT administration



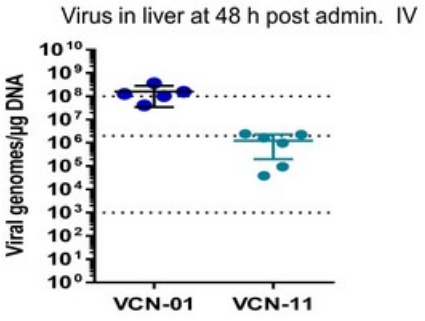
VCN-11 binds albumin

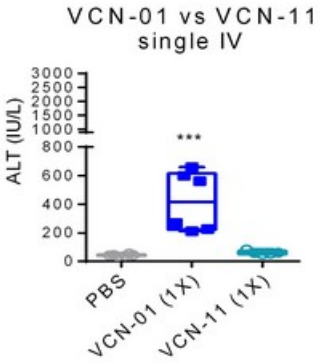


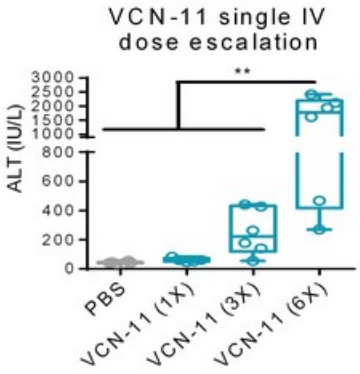
VCN-11 reduced hepatic toxicity compared to VCN-01

1X Dose = 4E10 vp/ mouse i.v.

Athymic nude mice bearing tumors



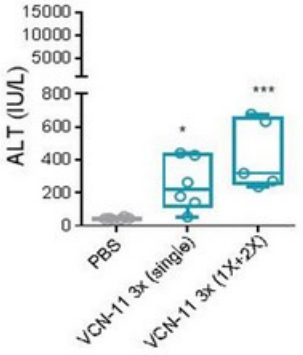




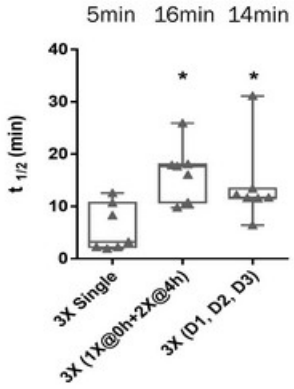
Reduced VCN-11 toxicity allows dose fractionation

Dose fractionation slightly increases hepatic toxicity

3X Dose = 1.2E11 vp/ mouse i.v.



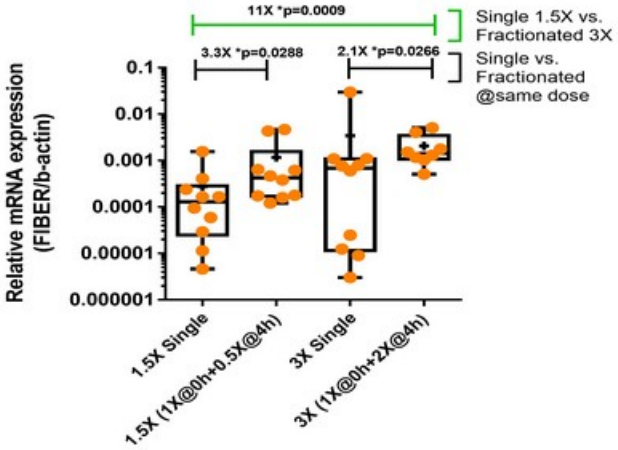
Increased $t_{1/2}$ for the second VCN-11 dose (mouse model)



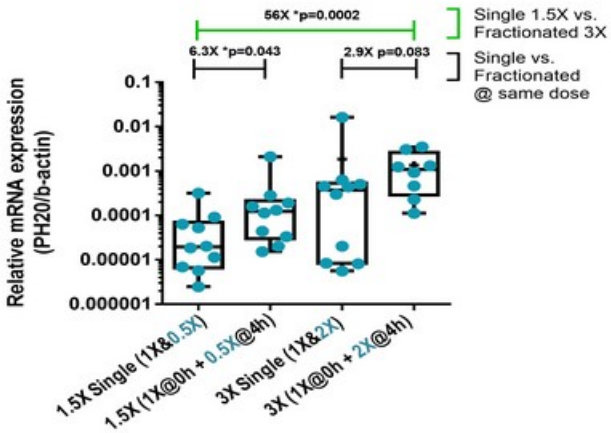
Dose fractionation increases VCN-11 bioavailability and improves tumor targeting

- Pre-dose with an oncolytic virus (ICOVIR15KABD) not expressing PH20 @ 1X = 4E+10vp/animal to block liver kupffer cells
- Post-dose with VCN-11 that expresses PH20

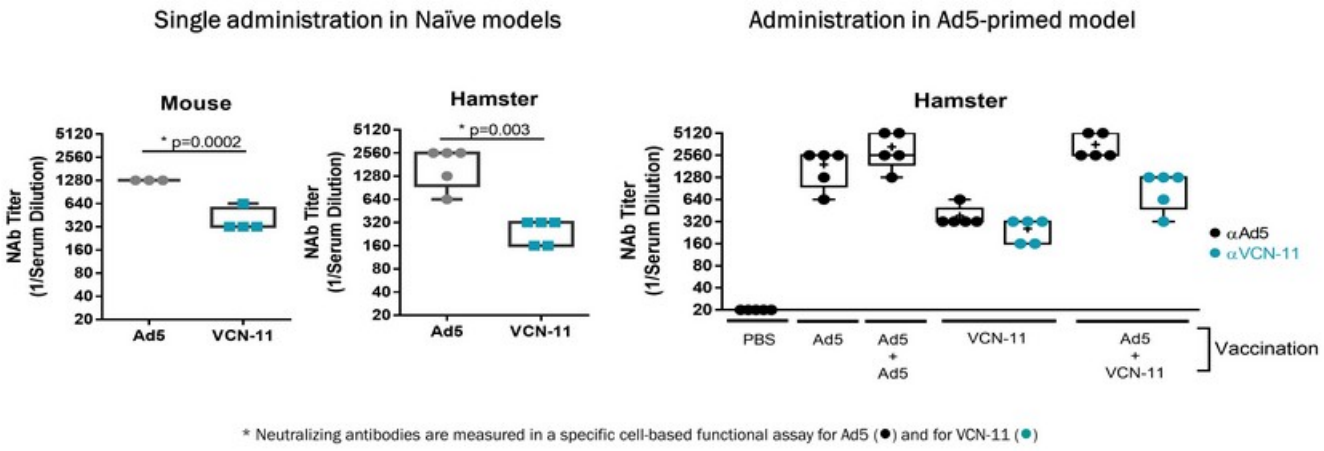
Fiber mRNA in tumor (accumulated dose)



PH20 mRNA in tumor (availability of the post-dose)

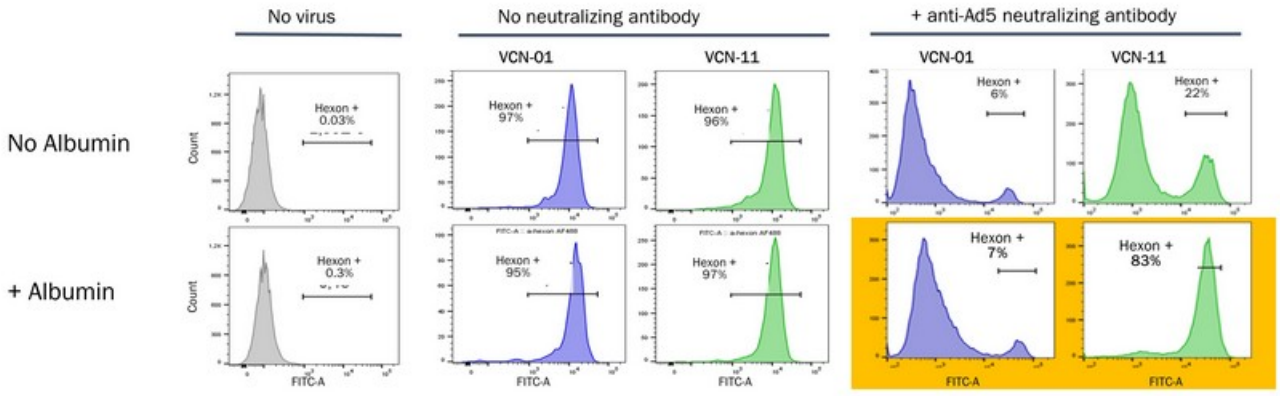


VCN-11 induces less NAbs compared to Ad5

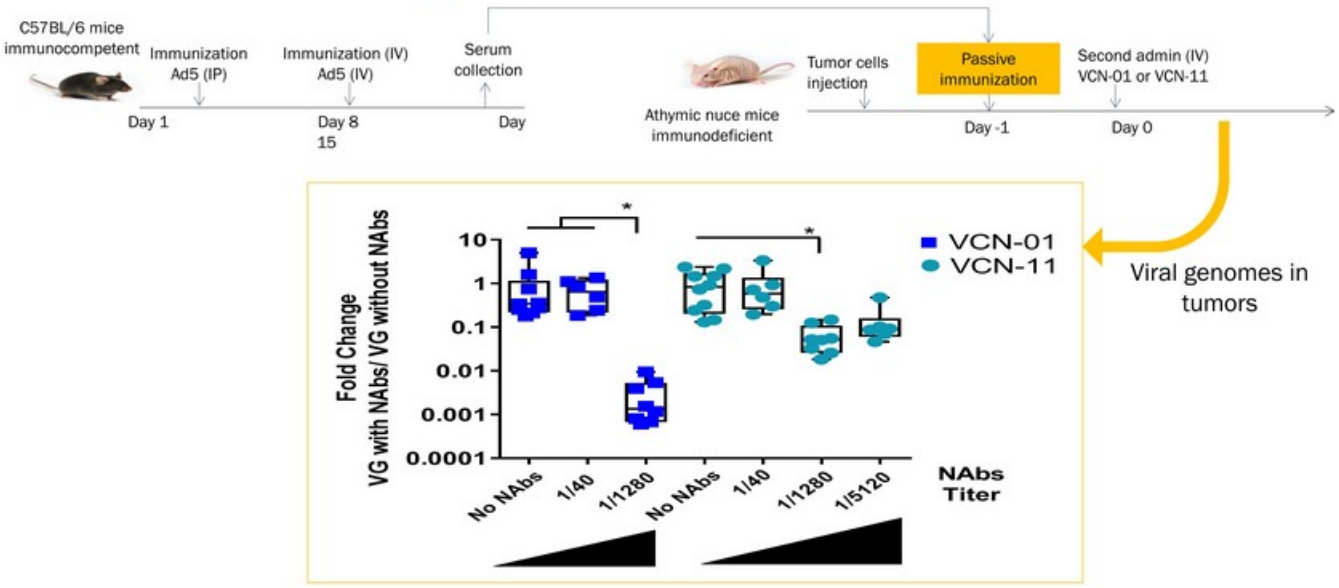


* Neutralizing antibodies are measured in a specific cell-based functional assay for Ad5 (●) and for VCN-11 (●)

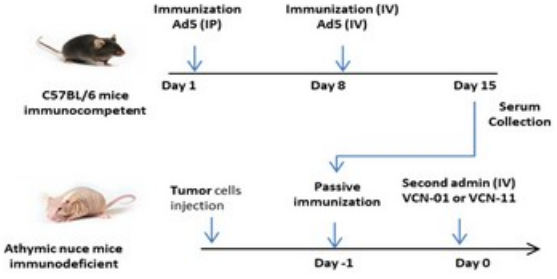
Albumin shields VCN-11 against anti-Ad5 NAbs (in vitro hexon flow cytometry)



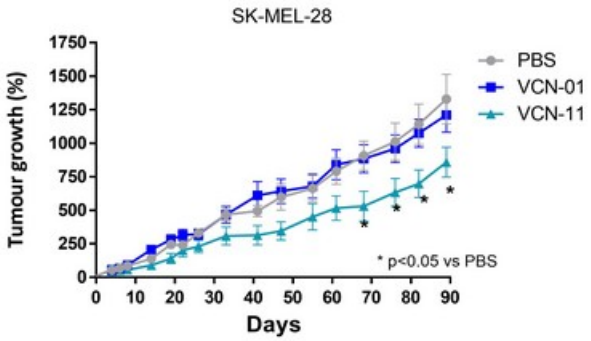
Albumin shields VCN-11 against anti-Ad5 NAbs in vivo



VCN-11 shows antitumor activity in the presence of anti-Ad5 NAbs

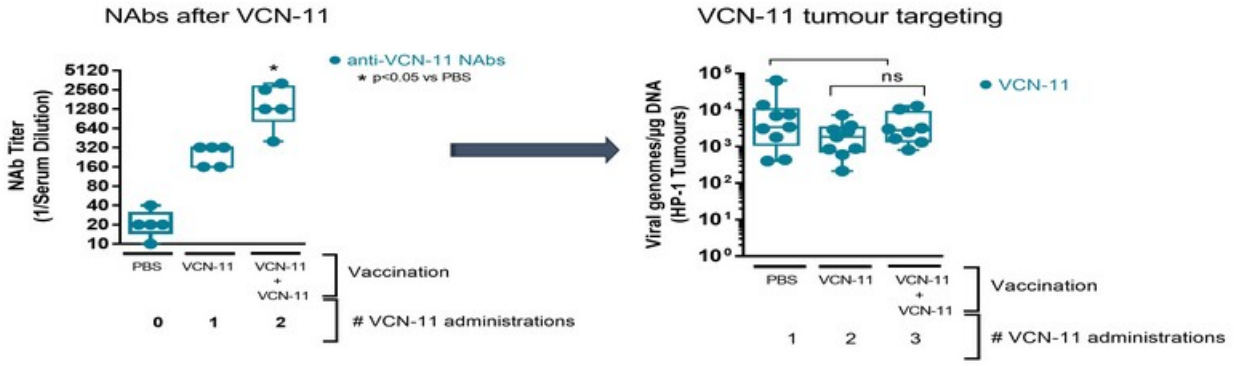


Serum of immunized immuno-competent mice was injected at day -1, giving rise to **a total neutralizing titer of 1/640-1/1280 at day 0**.

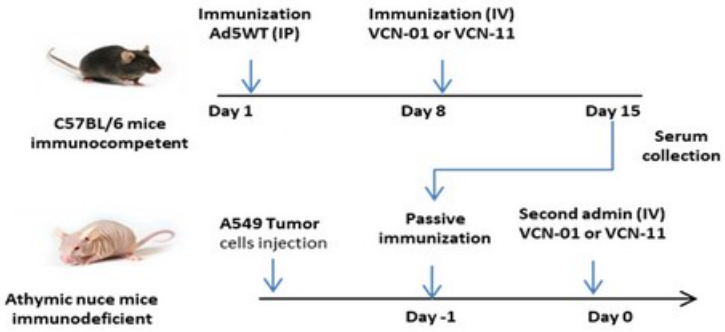


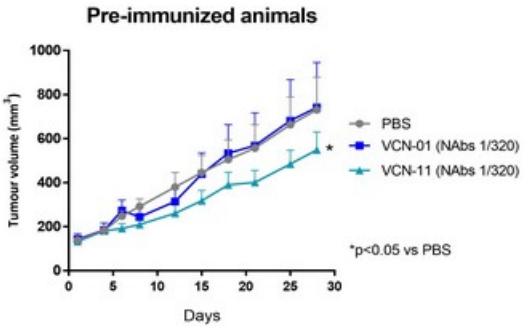
Sustained VCN-11 tumor targeting despite high NAbs upon multiple i.v. doses

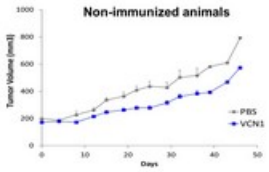
Immunocompetent
Syrian Hamster



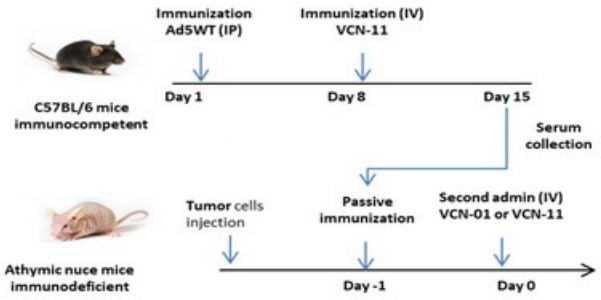
VCN-11 antitumor activity in the presence of antiAd5+antiVCN-11 NAbs

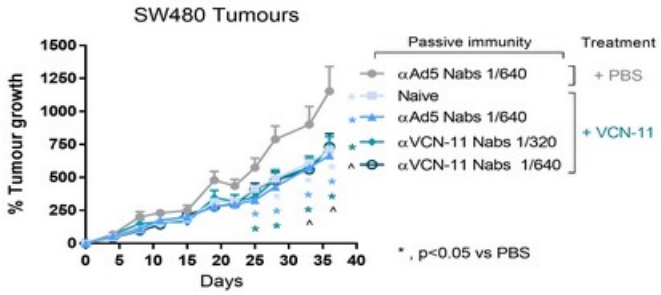






VCN-11 antitumor activity in the presence of antiAd5+antiVCN-11 NAbs





Conclusions

- VCN-11 expresses functional hyaluronidase.
- Reduced hepatic toxicity of the ABD-modified virus allows to “fractionate” VCN-11 administration which improves circulating half-life and tumor targeting.
- VCN-11 administration results in lower levels of neutralizing antibodies.
- VCN-11 reaches tumors and is effective after systemic administration in the presence of NAbs
- VCN-11´s albumin shield from NAbs allows effective readministration.

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Luís Rojas
Gabriel Capellà

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Maria V. Maliandi
Sheila Connelly
Michael Kaleko
Frank Tufaro
Manel Cascalló

Miriam Bazan-Peregrino
Sara Morgado