



# Corporate Overview

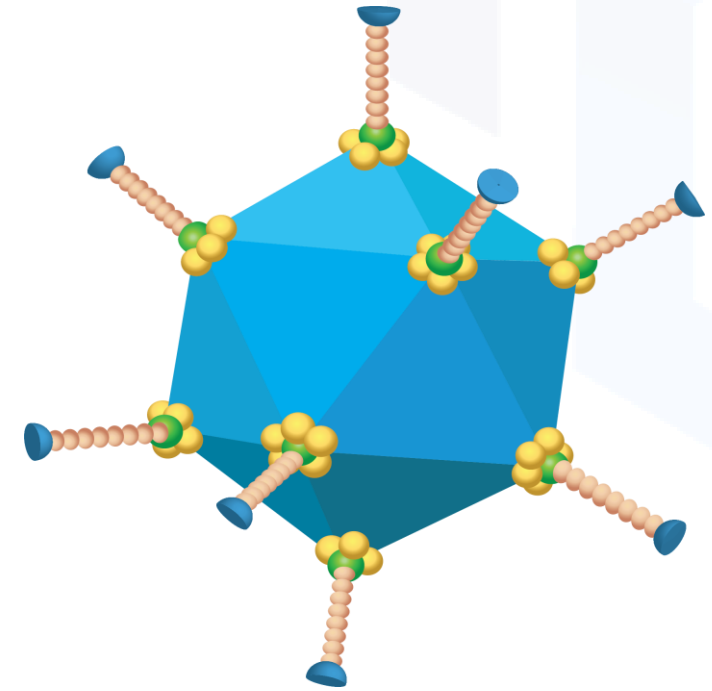
May 2025

# FORWARD LOOKING STATEMENTS

This presentation contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. In some cases forward-looking statements can be identified by terminology such as “may,” “should,” “potential,” “continue,” “expects,” “anticipates,” “intends,” “plans,” “believes,” “estimates,” and similar expressions, and include statements regarding oncolytic viruses (OVs) being promising cancer therapeutics; the multiple potential value opportunities for VCN-01; the regulatory status expected to facilitate VCN-01 development; potential access to a priority review voucher; the therapeutic potential of VCN-01 and other Theriva OVs; the ability of VCN-01 and other Theriva OVs to overcome key OV challenges; the potential of VCN-01 to enable immuno-oncology therapies in refractory tumors; the clinical advancement of VCN-01 and other Theriva OVs in diverse cancer indications (including pancreatic ductal adenocarcinoma, head and neck cancer, ovarian cancer, colorectal cancer, and retinoblastoma) and the projected milestones. Important factors that could cause actual results to differ materially from current expectations include, among others, the Company’s ability to enroll patients as planned and reach clinical trial milestones when anticipated; the Company’s ability to complete clinical trials on time and achieve the desired results and benefits; the Company’s product candidates demonstrating safety and effectiveness, including positive clinical data that demonstrates VCN-01 may lead to improved clinical outcomes for patients; the Company’s ability to obtain regulatory approval for commercialization of product candidates or to comply with ongoing regulatory requirements; regulatory limitations relating to the Company’s ability to promote or commercialize their product candidates for the specific indications; acceptance of product candidates in the marketplace and the successful development, marketing or sale of the Company’s products; developments by competitors that render such products obsolete or non-competitive; the Company’s ability to maintain license agreements; the continued maintenance and growth of the Company’s patent estate; the ability to continue to remain well financed; and other factors described in the Company’s Annual Report on Form 10-K for the year ended December 31, 2024 and its other filings with the SEC, including subsequent periodic reports on Forms 10-Q and current reports on Form 8-K. The information in this release is provided only as of the date of this release, and Theriva Biologics undertakes no obligation to update any forward-looking statements contained in this release on account of new information, future events, or otherwise, except as required by law.

# Theriva™ Biologics

develops unique  
oncolytic virus therapeutics  
targeting solid tumors



**VCN-01**  
(zabilugene almadenorepvec)

# OVERVIEW



**VCN-01** Completed Phase 2b clinical trial in first-line metastatic pancreatic cancer in combination with SoC chemotherapy



**VCN-01** Phase 1 clinical trials support multiple additional indications (CRC, HNSCC, Rb) and combinations (ICI & CAR-T cells)









**VCN-X** innovative oncolytic virus discovery engine enabling development of a distinct product pipeline

## Financial Snapshot

Exchange	NYSE American
Ticker	TOVX
Cash (12/31/2024)	\$11.6M
Projected cash runway	Q3 2025
Average Daily Volume (3M)	55.8k <sup>1</sup>
Locations	Rockville, MD / Barcelona, Spain

# THERIVA PIPELINE

Candidate	Target	Pre-IND	Phase 1	Phase 2	Phase 3	Sites	Status*
<b>VCN-01</b> Selective, Stroma Degrading OV	Pancreatic Cancer (IV) with gemcitabine/nab-paclitaxel					Multicenter Spain, USA	<b>Phase 2b enrollment complete</b> Orphan Drug Designation US, EU Fast Track Designation US
	Retinoblastoma (IVit)					 HOSPITAL MATERNOINFANTIL UNIVERSITAT DE BARCELONA	<b>Phase 1 Complete, CSR in preparation</b> Orphan Drug Designation US, EU Rare Pediatric Disease Designation US
	HNSCC (IV) + durvalumab					 Institut Català d'Oncologia	<b>Phase 1 Complete, CSR in preparation</b>
	Brain tumors (IV)					 LEEDS	<b>Phase 1 Study On-going</b>
<b>VCN-X and Albumin Shield OVs</b>	Solid tumors (IV)					  Institut Català d'IC IDIBELL Institut d'Investigacions Biomèdiques Escuela de Investigación	<b>Preclinical Studies On-going</b>
<b>SYN-004<sup>[1]</sup></b> Oral $\beta$ -lactamase	Prevention of aGVHD in allo-HCT					 Washington University in St. Louis	<b>Phase 1b/2a On-going</b>
<b>SYN-020<sup>[2]</sup></b> Oral IAP	Potential indications include NAFLD/NASH, celiac, radiation enteritis						<b>Phase 1 Studies Complete</b>

# VCN-01 IS A UNIQUELY ENGINEERED HUMAN ADENOVIRUS 5

High dose, highly replicating virus designed to destroy cancer cells

Systemic

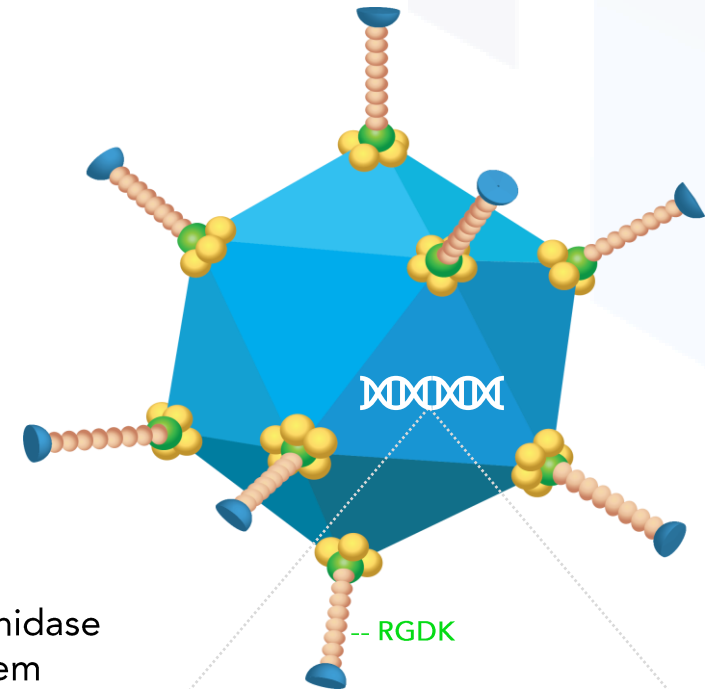
VCN-01 targets both **primary** and **metastatic** lesions

Selective

Virus replicates only in **tumor** cells  
Liver detargeted

Stroma Degrading

Replicating virus expresses **PH20** hyaluronidase  
Exposes solid tumors to the immune system  
and co-administered therapies



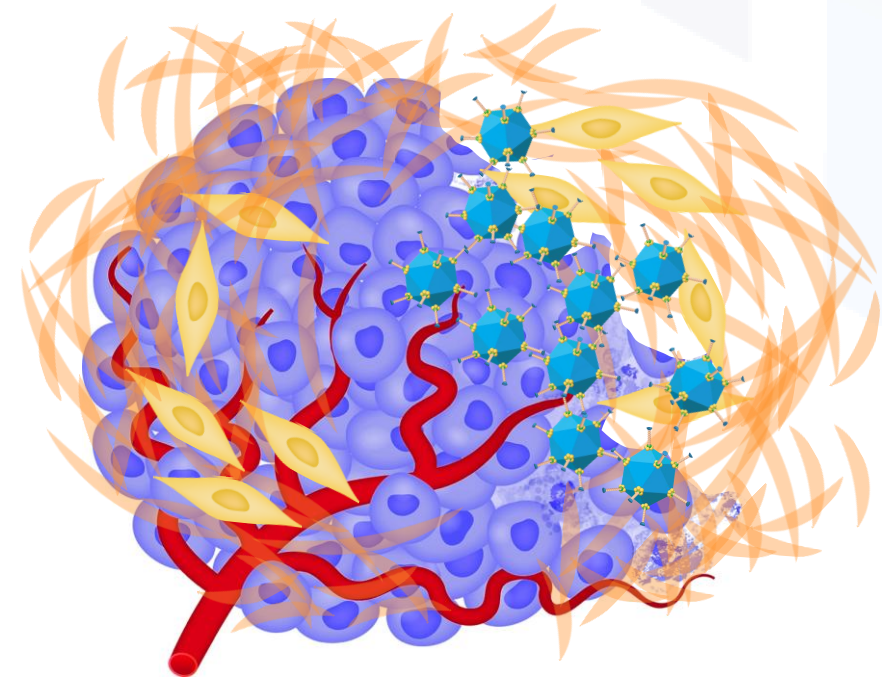
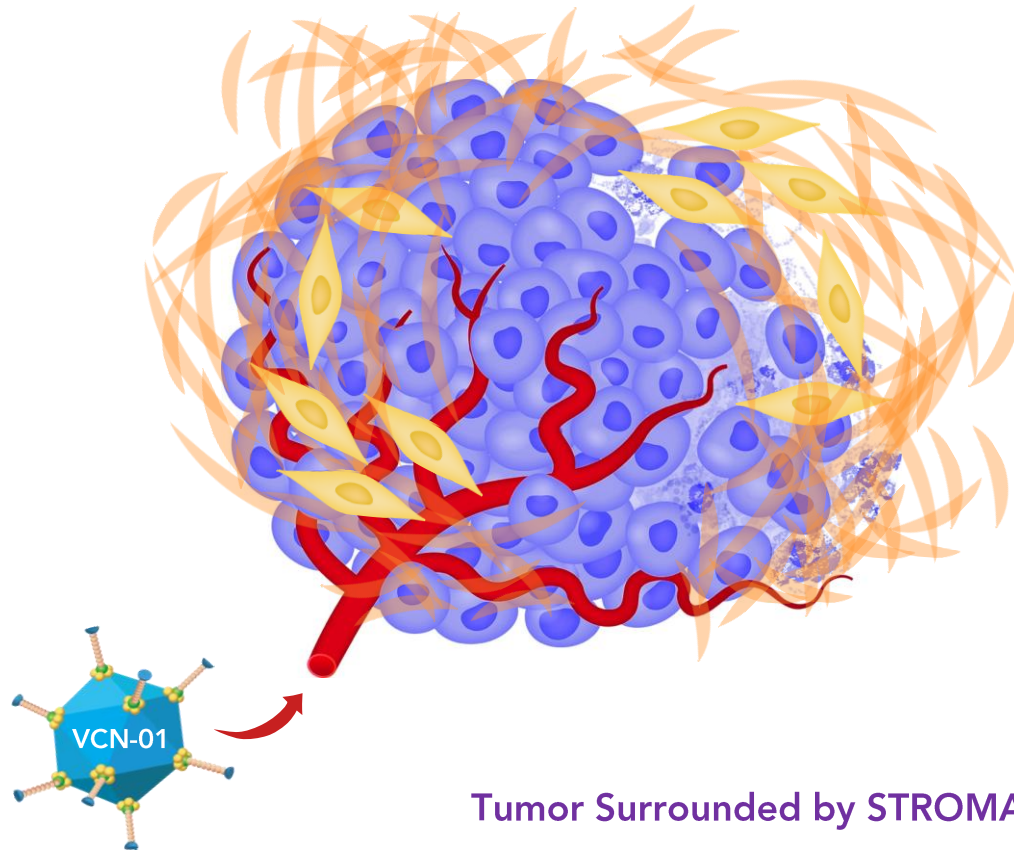
E2F binding +++ → E1a-Δ24 → MLP → PH20



# VCN-01 IS A UNIQUELY ENGINEERED HUMAN ADENOVIRUS 5

- 1 **SYSTEMIC** delivers VCN-01 to the primary tumor and metastases and detargets the liver

- 2 **SELECTIVE** replication at very high levels lyses tumor cells directly without harming healthy tissues



Tumor Surrounded by STROMA



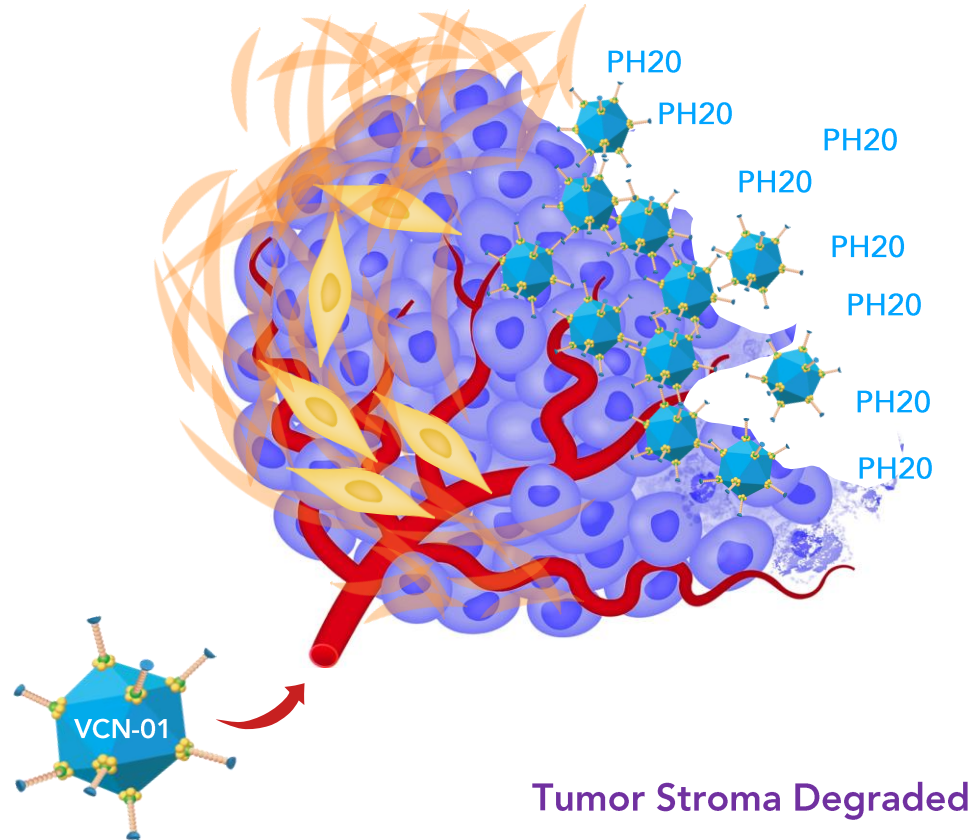
Stroma



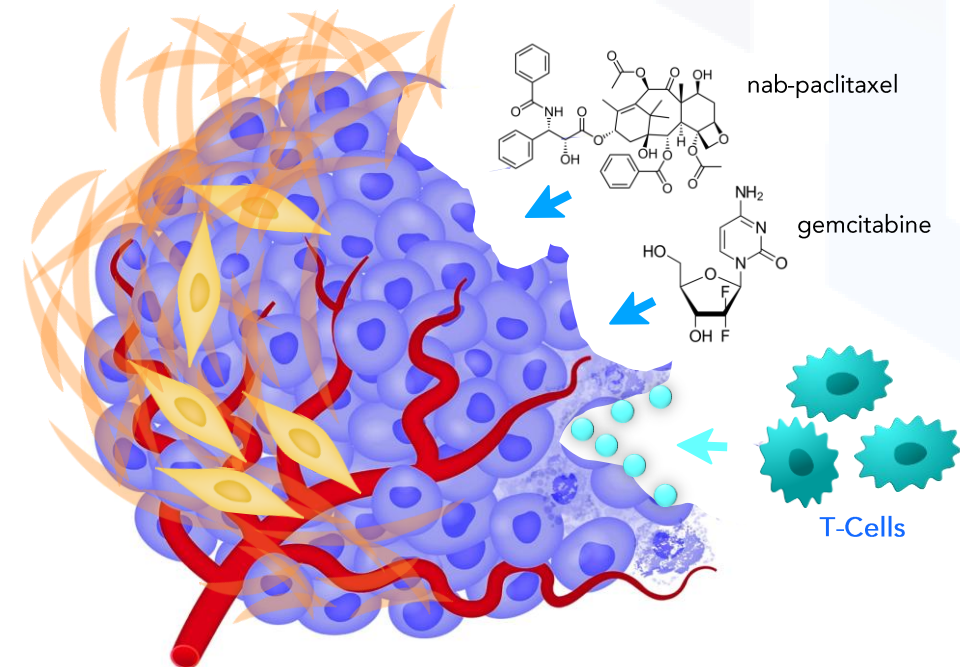
Cancer Associated  
Fibroblast

# VCN-01 DESIGNED TO HAVE MULTIPLE ANTI-TUMOR ACTIONS

- 3 **STROMA** degradation by PH20 facilitates solid tumor access and destruction by coadministered cancer therapies



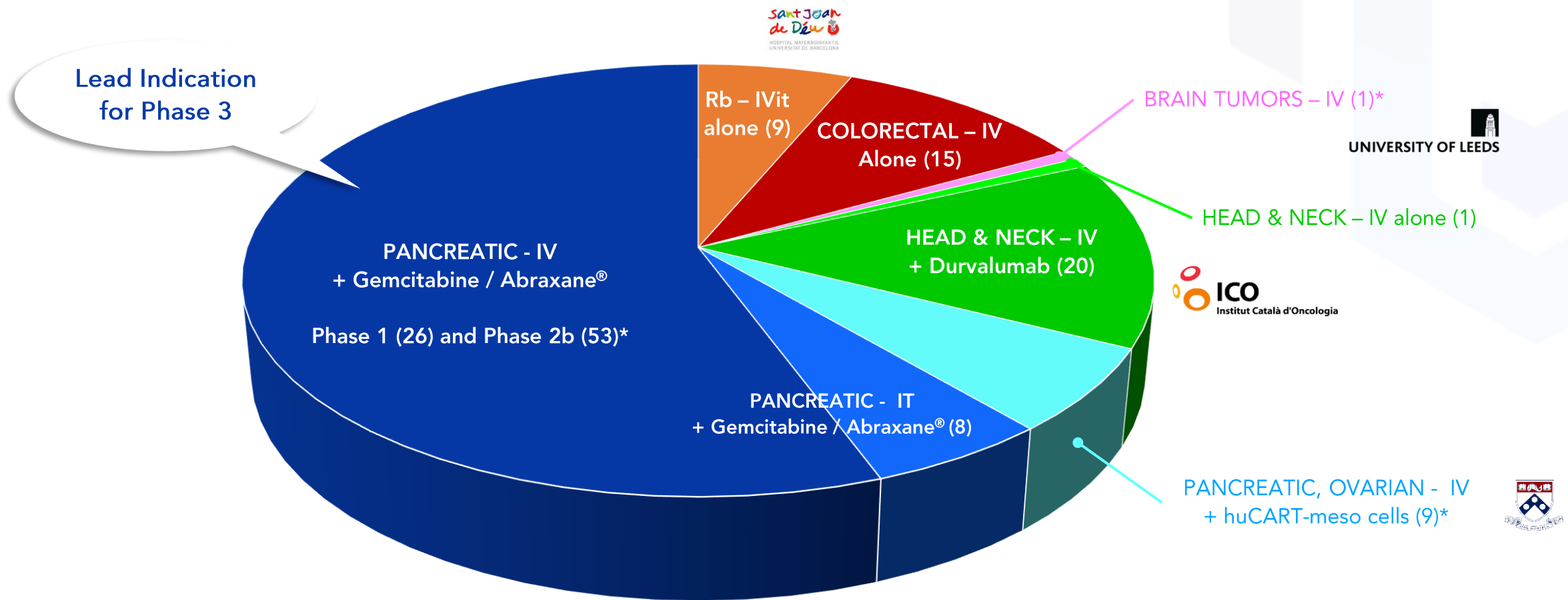
- 4 **IMMUNOGENIC** actions of VCN-01 turn "cold" tumors "hot" and elicit an anti-tumor immune response





# VCN-01 EXTENSIVE CLINICAL PROGRAM

142 patients treated with VCN-01 to date in multiple indications and combinations



(Number of VCN-01 Patients Treated in Parentheses)



## VCN-01 IN METASTATIC PANCREATIC CANCER

# VCN-01 LEAD INDICATION PANCREATIC CANCER

## Highly fatal cancer protected by dense tumor stroma

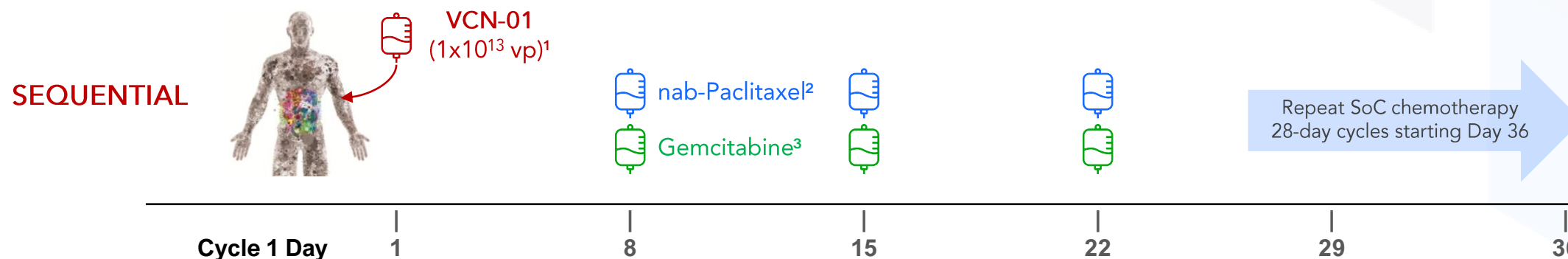
- Orphan disease, highest mortality of all solid tumors
  - Median survival 8-11 months for metastatic disease<sup>1,2</sup>
  - USA est. 66,440 new cases and 51,750 deaths in 2024<sup>3</sup>
- Hyaluronic acid in stroma is associated with reduced treatment efficacy and poor prognosis<sup>4</sup>
  - VCN-01 designed to degrade hyaluronic acid
- Incidence is growing worldwide
  - Est. treatment market ~\$2.9B (2024) ~\$6.0B (2030)<sup>5</sup>



Pancreatic adenocarcinoma resected from the pancreas body and tail

# PREFERRED VCN-01 DOSING REGIMEN ESTABLISHED IN PHASE 1

## Dose escalation in patients with metastatic pancreatic cancer



### Encouraging clinical profile

Primary AEs fever, flu-like illness, reversible increase in liver enzymes

Survival and response rates better than published results for gemcitabine/nab-paclitaxel SoC

### Clinical evidence of proposed MOA

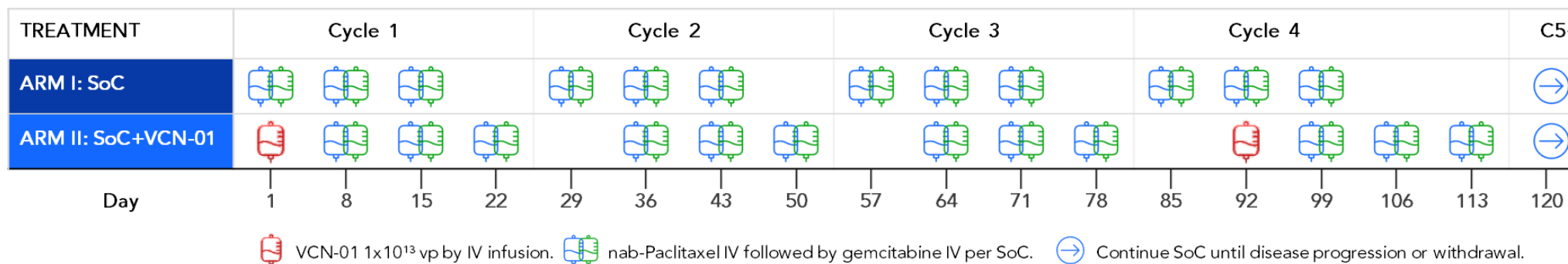
VCN-01 viral genomes and increased immune markers detected in tumor biopsies

VCN-01 tumor penetration and replication indicated by persistent systemic PH20

# VIRAGE PANCREATIC CANCER PHASE 2B CLINICAL TRIAL

## Multicenter, open-label, randomized, controlled trial (NCT05673811)

- Patients with newly-diagnosed metastatic pancreatic ductal adenocarcinoma ([first line](#))
- Direct comparison of up to [two doses](#) of VCN-01 with gemcitabine/nab-paclitaxel standard of care (SoC) chemotherapy to SoC chemotherapy alone (randomized 1:1)
- Primary endpoints [overall survival](#), VCN-01 AE profile and tolerability
- Secondary endpoints include [progression free survival](#), duration of response





# VIRAGE ENROLLMENT

Parameter	Spain	USA	Total
<b>Sites Open</b>	10	7	<b>17</b>
<b>Screened</b>	131	40	<b>171</b>
<b>Screen Failure</b>	42 (32%)	17 (43%)	<b>59 (35%)</b>
<b>Randomized</b>	89	23	<b>112</b>
SoC	44	11	<b>55</b>
VCN-01 + SoC	45	12	<b>57</b>
<b>Treated*</b>			
SoC	41	7	<b>48</b>
VCN-01 + SoC	39	9	<b>48</b>

[Standard of care \(SoC\)](#) is gemcitabine / nab-paclitaxel chemotherapy in repeated 28-day cycles

\*Patients received at least one dose of SoC in each arm and comprise the [Full Analysis Set](#)

Five (5) additional patients received one dose of VCN-01 but no doses of SoC and are included in the Safety Population

# VIRAGE BASELINE DEMOGRAPHICS

Patients who received at least one dose of SoC in each Arm (FAS)

		Statistics	SoC (n=48)	VCN-01 + SoC (n=48)	Combined (n=96)
Age (years)		n	48	48	96
		Mean (SD)	69.5 (8.25)	66.0 (8.97)	67.8 (8.75)
		Median	68.5	66.0	67.5
Gender					
	Male	n (%)	22 (45.8)	23 (47.9)	45 (46.9)
	Female	n (%)	26 (54.2)	25 (52.1)	51 (53.1)
ECOG at randomization					
	0	n (%)	17 (35.4)	19 (39.6)	36 (37.5)
	1	n (%)	31 (64.6)	29 (60.4)	60 (62.5)
Body Mass Index (kg/m <sup>2</sup> )					
		Mean (SD)	25.69 (4.265)	23.84 (3.502)	24.76 (3.992)
		Median	25.65	23.70	24.05

# VIRAGE TREATMENT EMERGENT ADVERSE EVENTS

## VCN-01 related events occurring in ≥5% of patients

Preferred Term – No. Patients (%) <sup>a,b</sup>	All Grades		Grade 3-4	
	First Dose (n=53)	Second Dose (n=36)	First Dose (n=53)	Second Dose (n=36)
Pyrexia	31 (58.5%)	19 (52.7%)	1 (1.9%)	-
Nausea	16 (30.2%)	6 (16.6%)	-	-
Asthenia	15 (28.3%)	4 (11.1%)	1 (1.9%)	1 (2.8%)
Vomiting	14 (26.4%)	9 (25.0%)	-	-
Aspartate aminotransferase increased	10 (18.9%)	1 (2.7%)	5 (9.4%)	-
Alanine aminotransferase increased	9 (16.9%)	1 (2.7%)	4 (7.5%)	-
Influenza like illness	9 (16.9%)	1 (2.7%)	7 (13.2%)	-
Transaminases increased	8 (15.1%)	2 (5.5%)	4 (7.5%)	-
Platelet count decreased/Thrombocytopenia	7 (13.2%)	1 (2.7%)	1 (1.9%)	-
Decreased appetite	7 (13.2%)	1 (2.7%)	-	-
Diarrhea	7 (13.2%)	3 (5.5%)	-	-
Fatigue	5 (9.4%)	-	-	-
Chills	5 (9.4%)	7 (19.4%)	-	-
Lymphocyte count decreased	4 (7.5%)	1 (2.7%)	3 (5.7%)	-
Gamma-glutamyl transferase increased	4 (5.7%)	-	3 (5.7%)	-
Anemia	3 (5.7%)	-	1 (1.9%)	-
Cytokine release syndrome	3 (5.7%)	2 (5.5%)	-	-

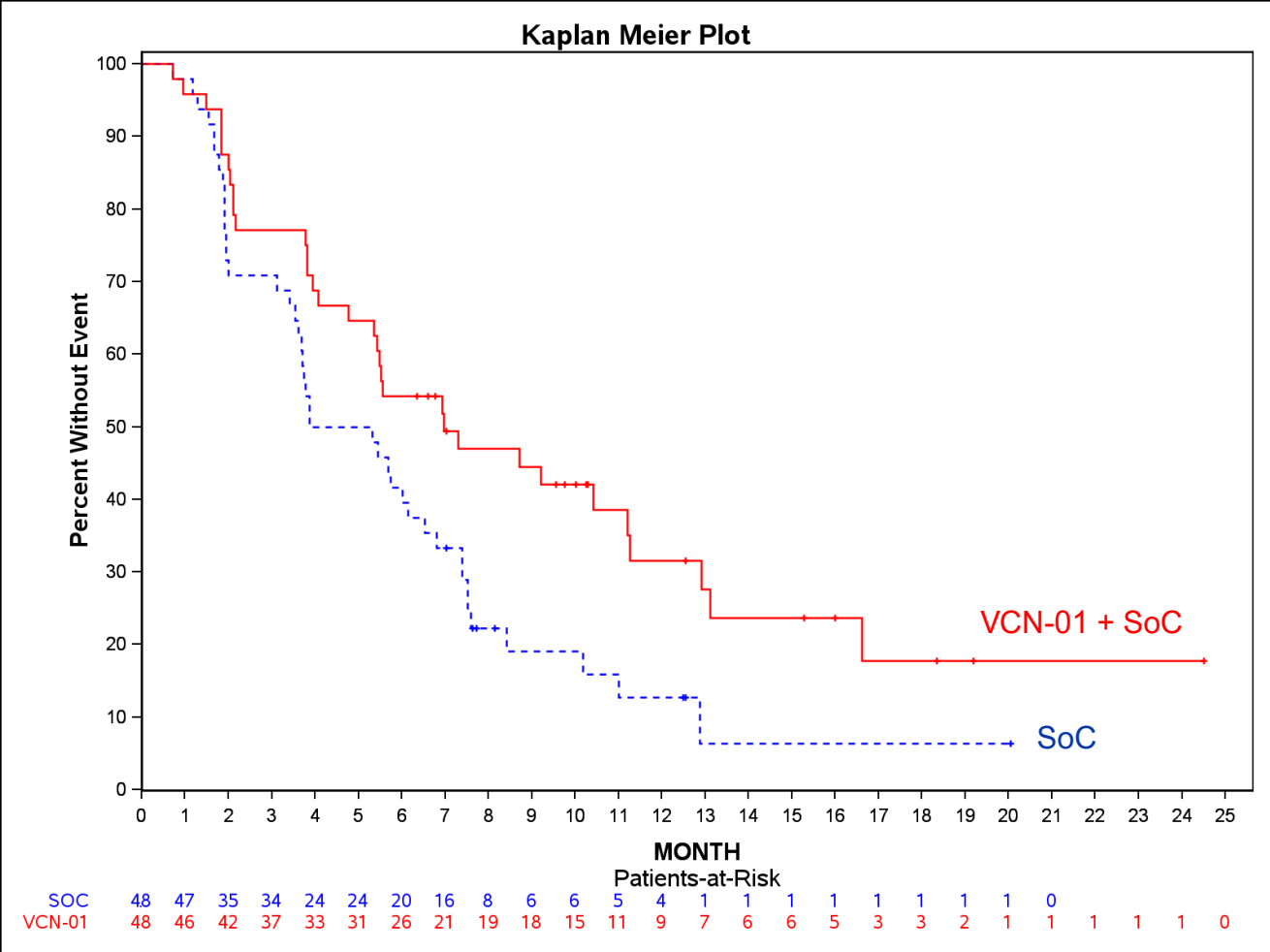
### **Additional Grade 3/4 AEs occurring <5%**

Treatment-induced liver injury 2 (3.8%)  
 Neutrophil count decreased 1 (1.9%)  
 Lipase increased 1 (1.9%)  
 Alkaline phosphatase increased 1 (1.9%)  
 Neutropenia 1 (1.9%)  
 Hypotension 1 (1.9%)

# VIRAGE SAFETY REVIEW BY INDEPENDENT DMC

- VIRAGE clinical data was reviewed on two occasions by an independent Data Monitoring Committee (DMC) who noted the following:
  - Intravenous VCN-01 was well tolerated in patients treated in this study
  - The most common VCN-01 related AEs (pyrexia, flu-like illness, vomiting, nausea, and elevated transaminases) were transient and reversible.
  - AEs were observed to be less frequent and of reduced CTCAE grade after the second VCN-01 dose compared to the first VCN-01 dose
  - The overall type and number of AEs in the VCN-01+SoC treatment group was as expected for the pancreatic cancer population, the duration of treatment, and the administration of an oncolytic virus

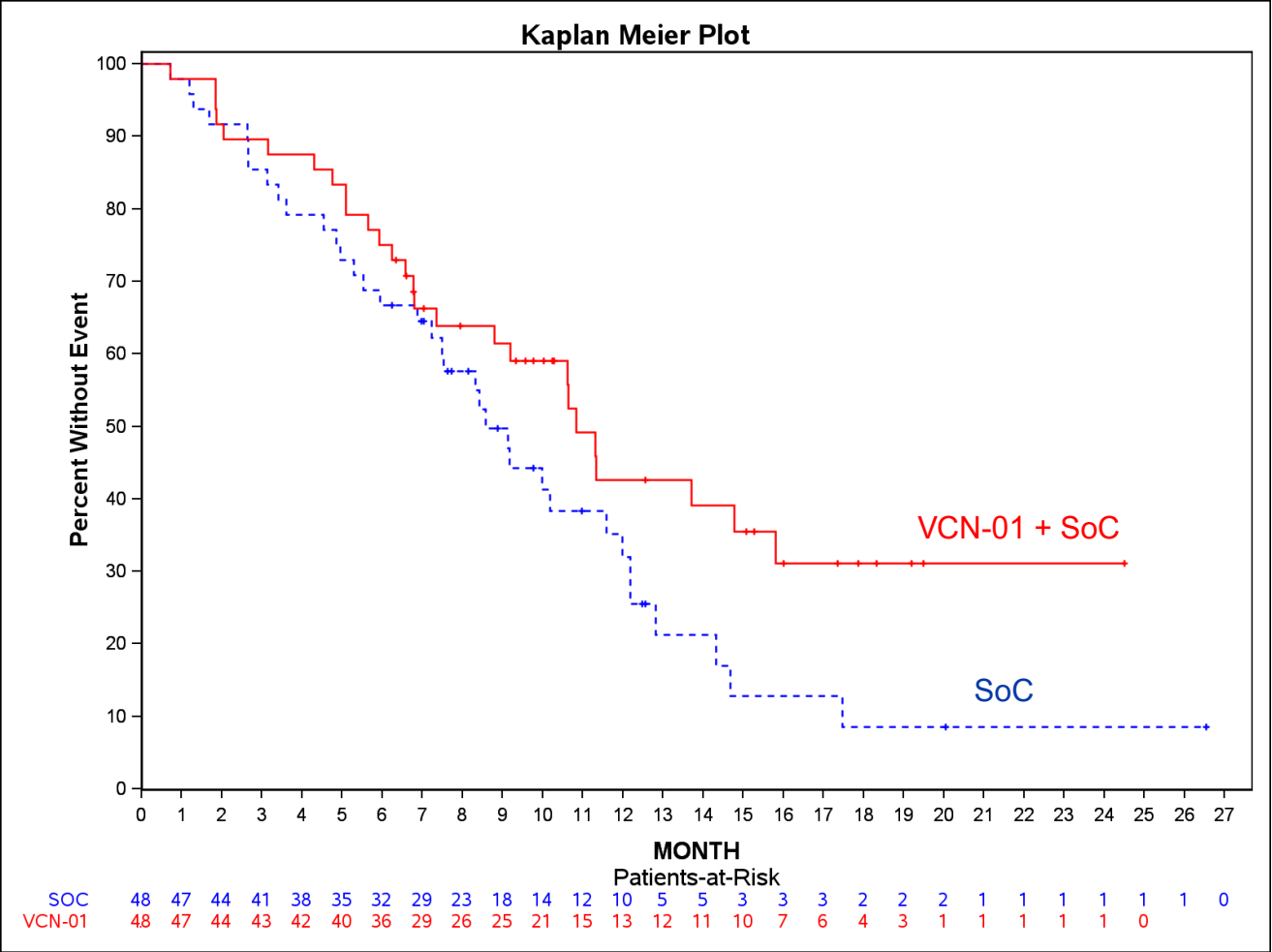
# INCREASED PROGRESSION-FREE SURVIVAL IN VCN-01+SOC ARM



Treatment Arm	Events / Total	Median (95% CI)	Adj HR (95% CI)
SoC	41 / 48	4.6 (3.5-6.5)	Ref.
VCN-01 + SoC	33 / 48	7.0 (4.8-11.2)	0.55 (0.34-0.88)
Logrank P-value: 0.0105			
+ Censor			

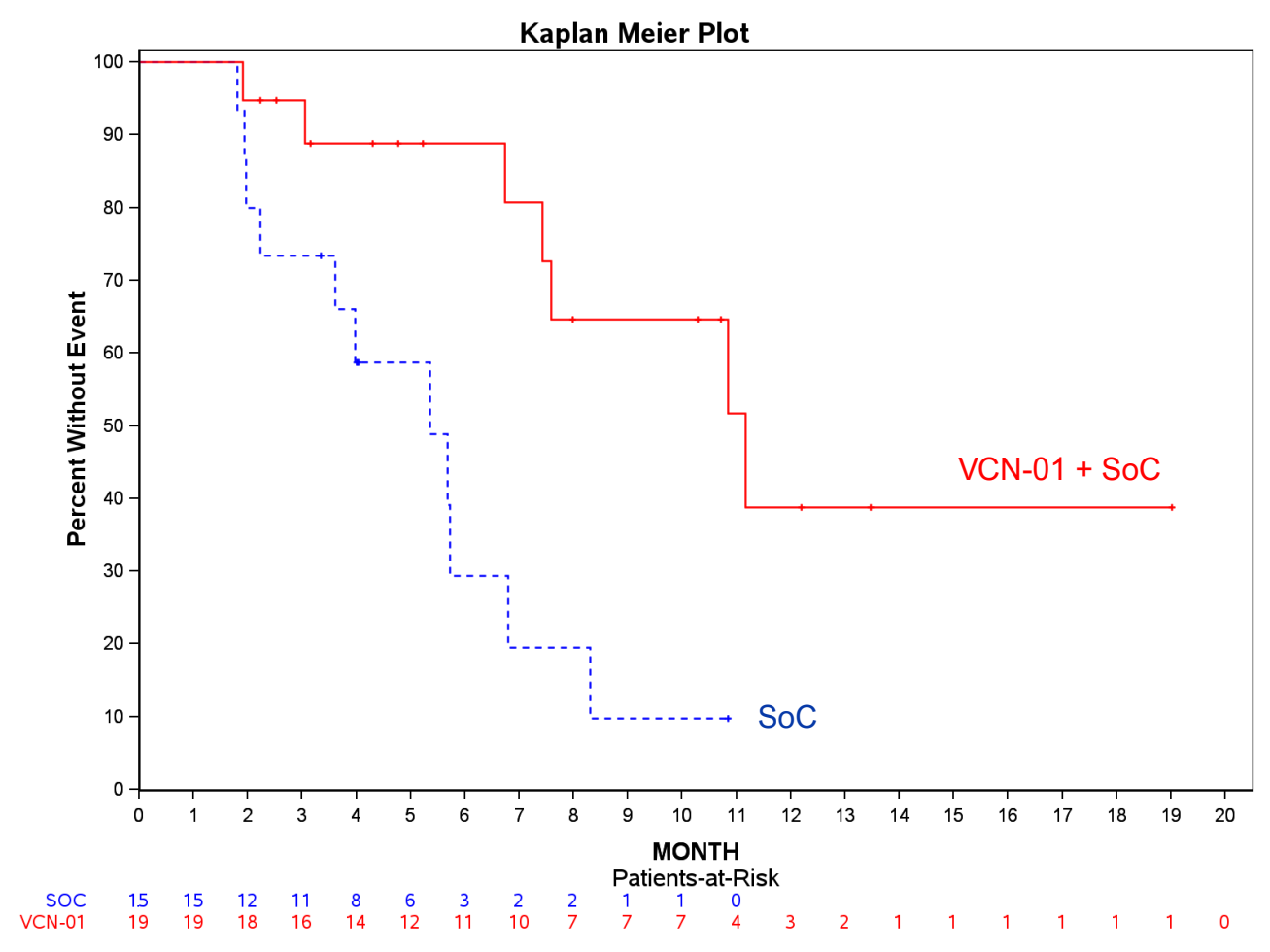


# INCREASED OVERALL SURVIVAL IN VCN-01+SOC ARM



Treatment Arm	Events / Total	Median (95% CI)	Adj HR (95% CI)
SoC	35 / 48	8.6 (6.9-11.6)	Ref.
VCN-01 + SoC	27 / 48	10.8 (7.4-15.8)	0.57 (0.34-0.96)
Logrank P-value: 0.0546			
+ Censor			

# DURATION OF RESPONSE DOUBLED IN VCN-01+SOC ARM



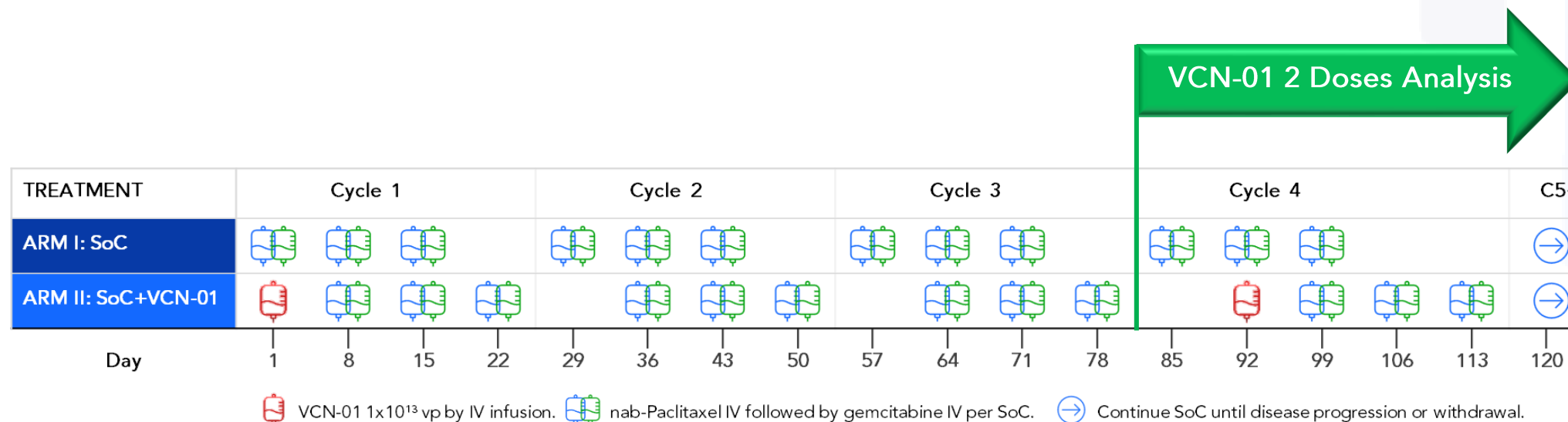
Treatment Arm	Events / Total	Median (95% CI)	Adj HR (95% CI)
SoC	11 / 15	5.4 (2.0-6.8)	Ref.
VCN-01 + SoC	7 / 19	11.2 (7.4-NE)	0.22 (0.08-0.62)

Logrank P-value: 0.0035

+ Censor

# VIRAGE ANALYSIS OF PTS RECEIVING TWO VCN-01 DOSES

## Evaluate the impact of the second VCN-01 dose



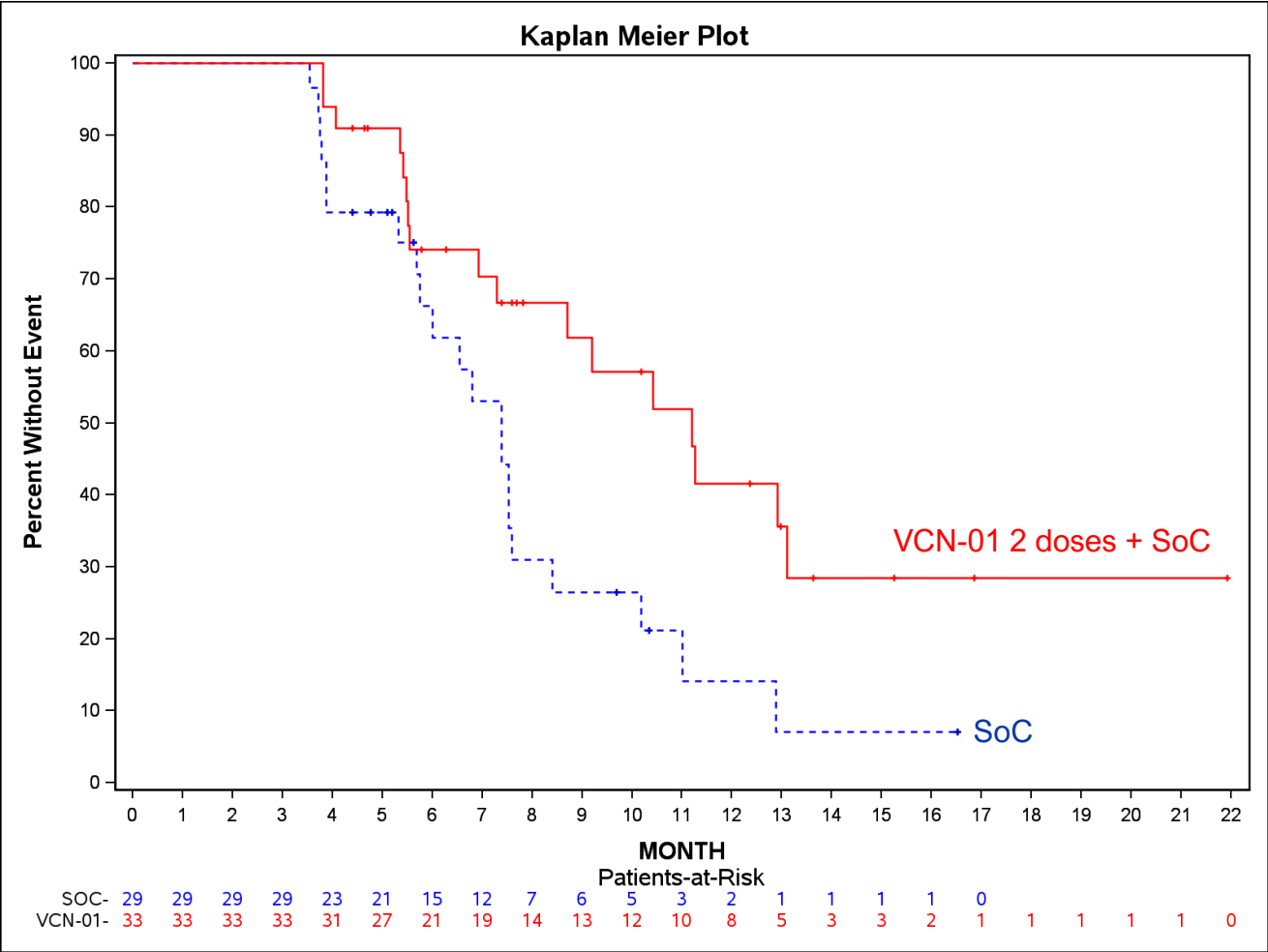
- Measure OS and PFS in patients who initiate the 4<sup>th</sup> treatment cycle
  - ARM I: Cycle 4 of gemcitabine/nab-paclitaxel SoC
  - ARM II: Second dose of VCN-01 followed by Cycle 4 of gemcitabine/nab-paclitaxel SoC

# VIRAGE DEMOGRAPHICS PTS RECEIVING TWO VCN-01 DOSES

## Comparison of patients who started the 4<sup>th</sup> treatment cycle

	Statistics	SoC	VCN-01 + SoC	Combined
No. Patients (% of cohort)	n (%)	29 (60.4)	34 (70.8)	63 (65.6)
Age (years)	Mean (SD)	68.1 (8.31)	65.8 (9.71)	66.9 (9.09)
	Median	66.0	66.0	66.0
Gender				
Male	n (%)	13 (44.8)	17 (50.0)	30 (47.6)
Female	n (%)	16 (55.2)	17 (50.0)	33 (52.4)
ECOG at randomization				
0	n (%)	14 (48.3)	15 (44.1)	29 (46.0)
1	n (%)	15 (51.7)	19 (55.9)	34 (54.0)
Body Mass Index (kg/m <sup>2</sup> )				
	Mean (SD)	24.94 (3.304)	23.78 (3.707)	24.31 (3.547)
	Median	25.60	23.65	23.70

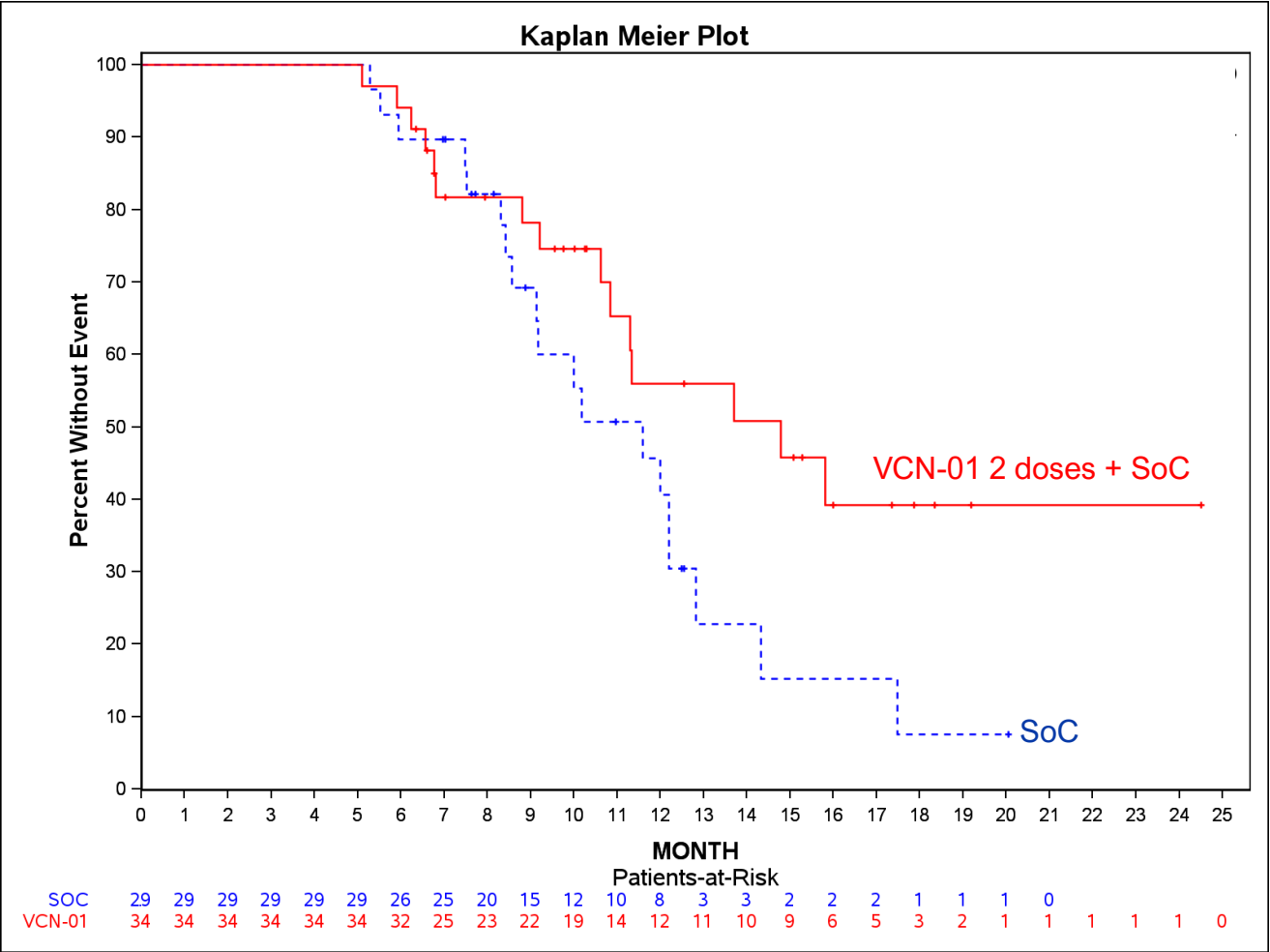
# IMPROVED PFS IN PTS RECEIVING TWO VCN-01 DOSES



Treatment Arm	Events / Total	Median (95% CI)	Adj HR (95% CI)
SoC	22 / 29	7.4 (5.7-8.4)	Ref.
VCN-01 x 2 + SoC	19 / 34	11.2 (7.3-16.6)	0.48 (0.25-0.91)
Logrank P-value: 0.0173			
+ Censor			



# IMPROVED OS IN PTS RECEIVING TWO VCN-01 DOSES



Treatment Arm	Events / Total	Median (95% CI)	Adj HR (95% CI)
SoC	19 / 29	11.6 (8.6-12.8)	Ref.
VCN-01 x 2 + SoC	15 / 34	14.8 (10.6-NE)	0.44 (0.21-0.92)
Logrank P-value: 0.0460			
+ Censor			

# VIRAGE RESULTS SUPPORT VCN-01 PHASE 3 TRIAL IN PDAC

- Enrolled a “real world” population of older and more fragile patients
- Acceptable AE profile consistent with prior VCN-01 clinical trials
- Increased OS, PFS, and DoR in VCN-01 plus gemcitabine/nab-paclitaxel SoC treatment group compared to SoC alone
  - Hazard ratios for OS (0.57), PFS (0.55), and DoR (0.22) compare favorably to values reported for NAPOLI 3 Phase 3 trial comparing NALIRIFOX with gemcitabine/nab-paclitaxel (0.83, 0.69, and 0.67 respectively)<sup>1</sup>
  - Second VCN-01 dose appears to confer additional survival benefit
- Regulatory advice received (FDA, EMA) on potential pivotal trial design
  - Orphan Drug Designation (FDA, EMA) and Fast Track Designation (FDA)

# VCN-X NEXT GENERATION OV DISCOVERY PLATFORM



# THERIVA OV PIPELINE DISCOVERY AND DEVELOPMENT

Advancing founders' decades of world leading OV innovation

## Common Features

Clinically-tested Adenovirus Expressing PH20  
Hyaluronidase to **Degrade Tumor Stroma**

+

Additional Transgene Payloads to Enhance  
Anti-tumor Immune Response and  
Potentially Enable **Single-Agent** therapy

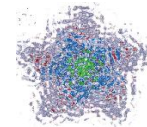
+ / -

**Albumin Shield™** To Prevent Neutralization by  
Anti-viral Antibodies and Facilitate IV Multidosing

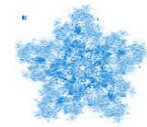
## Product Specific Features



**VCN-01 Hyaluronidase alone**



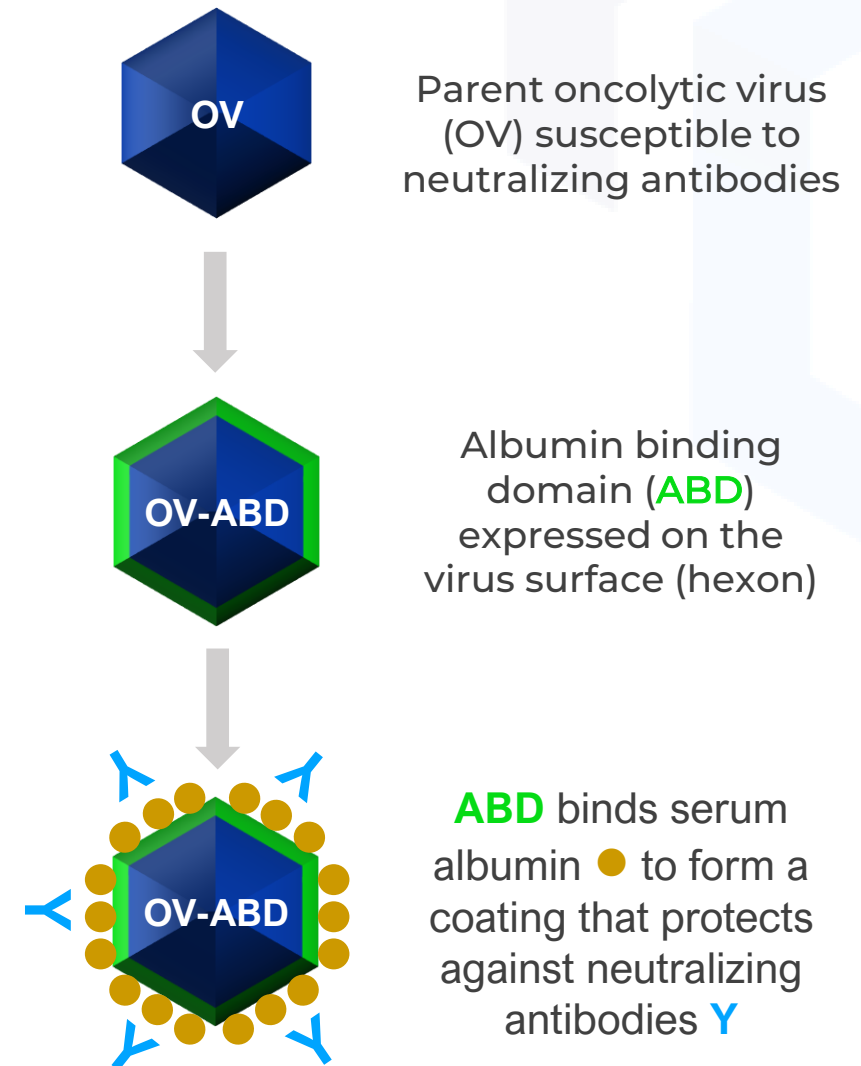
**VCN-12 Hyaluronidase + Toxins**



**VCN-11 Hyaluronidase + Albumin Shield**

# ALBUMIN SHIELD™ to ENHANCE OV SYSTEMIC DELIVERY

- Albumin Shield technology protects OVs as they travel to tumors after systemic administration<sup>1,2</sup>
- Albumin Shield modified OVs bind albumin in the patient's blood to form a protective coating
- Albumin Shield genetic modification allows parent and progeny virus to be albumin coated
- Albumin Shield may enable **multiple IV administrations** for hard-to-treat patients
- Albumin Shield first candidate VCN-11 is being prepared for a potential Phase 1 clinical trial





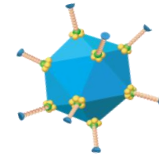


## THERIVA SUMMARY

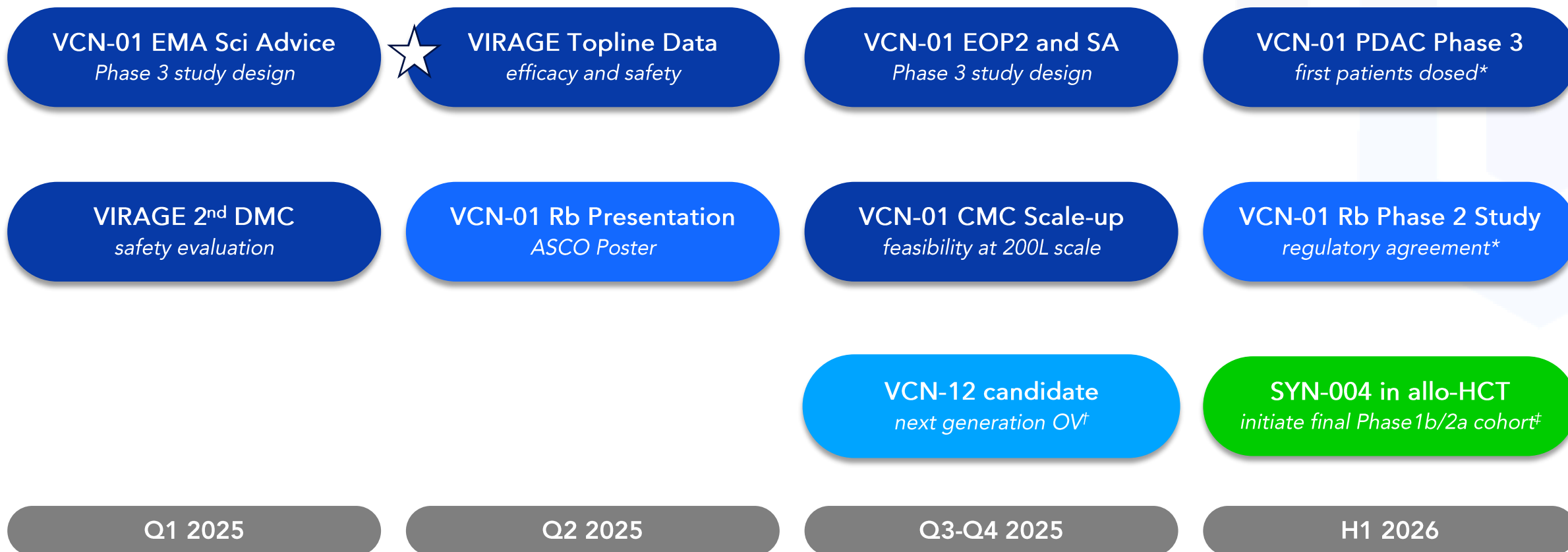
# THERIVA OV PORTFOLIO HIGHLIGHTS

## Multiple modes of action, indications and combinations

- Highly differentiated OV<sup>s</sup> designed to have multiple antitumor effects
  - Systemic administration, selective tumor replication, stroma degradation
- Multiple potential value opportunities for lead asset VCN-01
  - Phase 1-2 clinical data in different indications (PDAC, HNSCC, retinoblastoma) and diverse combinations (chemotherapy, CPI, CAR-T)
- Regulatory status expected to facilitate VCN-01 development
  - PDAC: Orphan Drug Designation (FDA, EMA), Fast Track designation (FDA)
  - Retinoblastoma: Orphan Drug Designation (EMA; FDA); Rare Pediatric Disease Designation (FDA: potential access to priority review voucher)
- Leading OV discovery engine advancing diverse new product candidates
  - Potent tumor killing with potential single agent efficacy



# ACHIEVEMENTS AND PROJECTED MILESTONES







# APPENDIX



# SEASONED LEADERSHIP TEAM



**Steven Shallcross**

Chief Executive Officer, Chief Financial Officer

Served as the Company's CEO since 2018 and CFO since joining the Company in 2015

Deep operational, financial and international biotech industry experience and proven track record of leading the financial development and strategy in the public sector

**Senseonics**

**VANDA**  
PHARMACEUTICALS INC.

**Innoco**ll

**nuo**  
THERAPEUTICS

**Theriva**  
BIOLOGICS



**Manel Cascalló PhD**

General Director, EU Subsidiary

Expertise in oncolytic adenovirus clinical development, received several patents for the use of adenovirus as antitumoral agents and authored many peer-reviewed scientific publications

Deep regulatory experience and serves as an independent expert for the European Medicines Agencies (EMA)

**VCN**  
BIOSCIENCES



**Vince Wachter PhD**

Head Corporate Development

Nearly 30 years leading corporate strategy, partnering, research, clinical development, and intellectual property programs for start-ups, small companies, and new business units within large companies

Development experience across oncology, infection, GI, metabolic diseases, transplantation, and drug delivery

**EASTMAN**

**Verva**  
Pharmaceuticals

# VCN-01 COMPARED TO OTHER ONCOLYTIC VIRUSES IN DEVELOPMENT

COMPANY	THERIVA BIOLOGICS	CG ONCOLOGY	GENELUX	ONCOLYTICS BIOTECH	REPLIMMUNE
Ticker	NYSE MKT: TOVX	NASDAQ: CGON	NASDAQ: GNLX	NASDAQ: ONCY	NASDAQ: REPL
Market Cap <sup>1</sup>	\$3.7M	\$2.07B	\$102.3M	\$48.5M	\$753.9M
Product	<b>VCN-01</b>	<b>Cretostimogene grenadenorepvec</b>	<b>Olvi-Vec</b>	<b>Pelareorep</b>	<b>RP1, RP2</b>
Virus	Adenovirus 5	Adenovirus 5	Vaccinia	Reovirus	Herpes Simplex
Type	DNA	DNA	DNA (enveloped)	RNA	DNA (enveloped)
Tumor selectivity mechanism	Selective replication (Rb-E2F dysfunction)	Selective replication (Rb-E2F dysfunction)	Low tumor IFN TK deletion	Low tumor IFN Ras activation	Low tumor IFN ICP34.5 deletion
Therapeutic Transgene	PH20	GM-CSF	..	..	GM-CSF, GALV-GP R(-), anti-CTLA-4
Lead Indication (Ph)	Pancreatic (2b)	Bladder (3)	Ovarian (3)	Pancreatic, GI (2b)	Melanoma (3)
Route	IV	IVESIC	IP	IV	IT
Dose	1x10 <sup>13</sup> vp <sup>2</sup>	1x10 <sup>12</sup> vp	3x10 <sup>9</sup> pfu	4.5x10 <sup>10</sup> TCID <sub>50</sub>	1x10 <sup>7</sup> pfu/mL
Stroma Degrading	Yes	No	No	No	No
Biomarker	PH20	..	β-GAL, β-GLU, GFP	..	..





## VCN-01 IN PANCREATIC CANCER

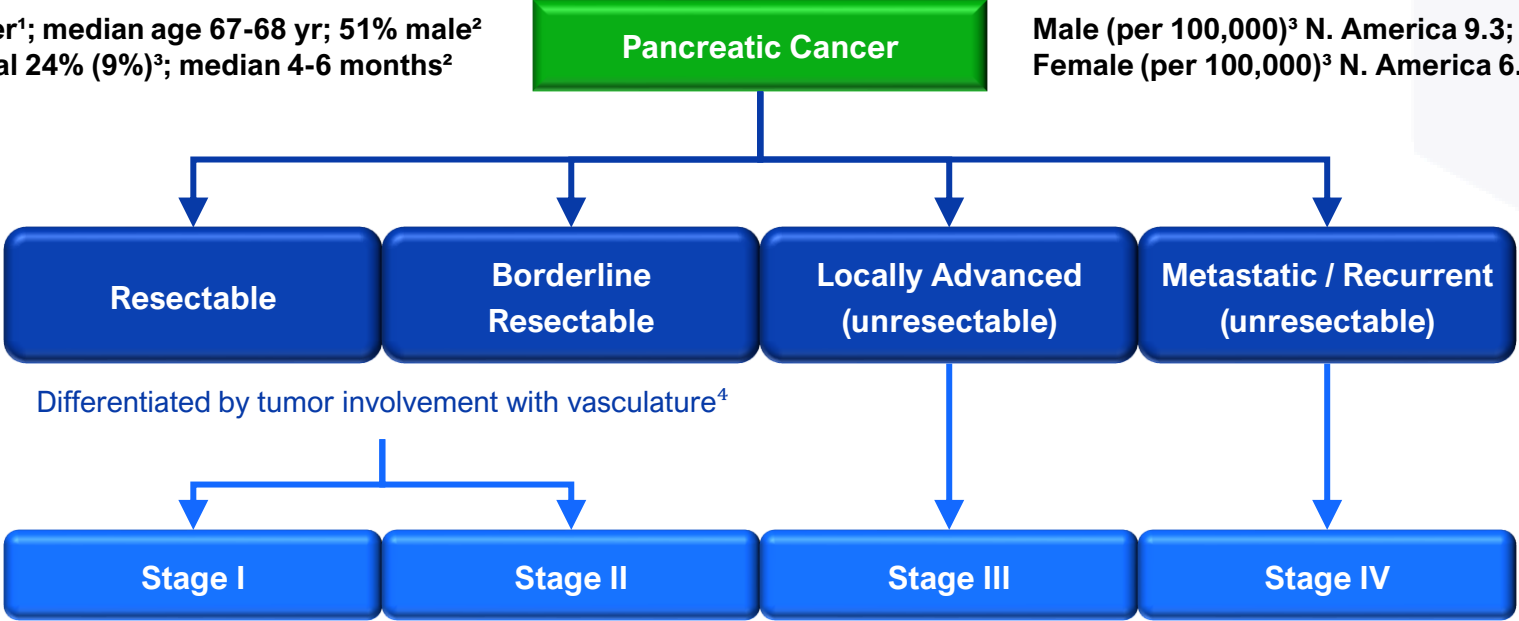


# PANCREATIC CANCER STAGING

PDAC >90% pancreatic cancer<sup>1</sup>; median age 67-68 yr; 51% male<sup>2</sup>  
 1-year (5-year) overall survival 24% (9%)<sup>3</sup>; median 4-6 months<sup>2</sup>

## Pancreatic Cancer

Male (per 100,000)<sup>3</sup> N. America 9.3; W. Europe 9.9; E. Asia 7.0  
 Female (per 100,000)<sup>3</sup> N. America 6.9; W. Europe 7.4; E. Asia 4.8



### AJCC Stage

#### T-N-M<sup>5</sup>

IA	IB	IIA	IIB	III	IV
T1 N0 M0	T2 N0 M0	T3 N0 M0	T1-3 N1 M0	T1-3 N2 M0 T4 NX-2 M0	TX-4 NX-2 M1

#### Median Age, yr (range)<sup>6</sup>

66 (30-88)	66 (31-89)	68 (31-93)	66 (30-95)	67 (31-94)	67 (30-95)
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#### Male (Female), %<sup>6</sup>

51 (49)	48 (52)	50 (50)	51 (49)	50 (50)	54 (46)
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#### Proportion of PDAC, %<sup>2</sup>

1.3%	4.4%	11.5%	16.3%	10.6%	<b>56.0%</b>
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#### 5-Year Survival, %<sup>2</sup>

31.7%	11.8%	9.0%	8.7%	1.9%	<b>0.5%</b>
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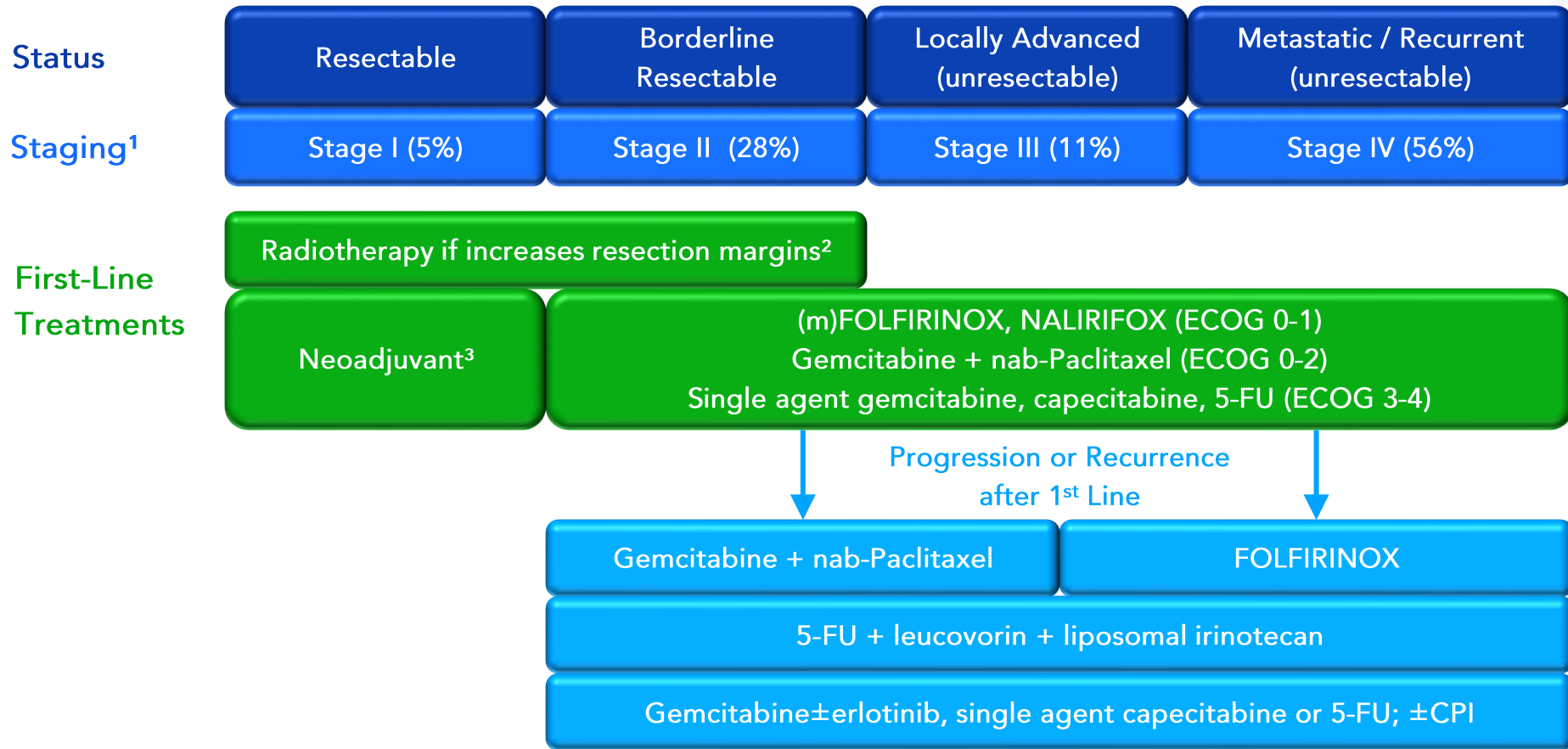
#### Pancreas Head, %<sup>6</sup>

61%	58%	77%	85%	75%	55%
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<sup>1</sup>PDAC pancreatic ductal adenocarcinoma. Cancers in the pancreas head (~70%) are diagnosed earlier than cancers in the body or tail (each ~15%), which have a worse prognosis, Sarantis (2020) *World J Gastrointest Oncol* **12**:173-181. <sup>2</sup>Bengtsson (2020) *Sci Rep* **10**:16425.

<sup>3</sup>GLOBOCAN 2020 survey of persons 0-74 years. Ushio (2021) *Diagnostics* **11**:562. <sup>4</sup>Toesca (2018) *Int J Radiation Oncol Biol Phys* **100**:1155-1174. <sup>5</sup>American Joint Committee on Cancer Tumor size, Nodal involvement, Metastasis. <sup>6</sup>Yu (2015) *Gut* **64**:1783-9.

# PANCREATIC CANCER CURRENT TREATMENTS



Additional treatments are available for small subsets of patients with gene mutations such as gBRCAm , NRG1 fusion

<sup>1</sup>Bengtsson (2020) *Sci Rep* 10:16425. <sup>2</sup>Used in <20% of PDAC cases. <sup>3</sup>Identical to first-line chemotherapy. CPI checkpoint inhibitor for cancers with microsatellite instability or deficient mismatch repair. ECOG Eastern Cooperative Oncology Group Performance Status. (m)FOLFIRINOX (modified) leucovorin+5-FU+irinotecan+oxaliplatin. nab-Paclitaxel nanoparticle albumin-bound paclitaxel. NALIRIFOX leucovorin+ 5-FU+liposomal irinotecan+oxaliplatin. Adapted from Tempero (2021) *J Natl Compr Canc Netw* 19:439.

# VIRAGE COMPARED TO NALIFIROX NAPOLI 3

	Statistics	VIRAGE		NAPOLI 3 <sup>1</sup>	
Treatment Arm		VCN-01+Gem/Nab	Gem/Nab	NALIRIFOX	Gem/Nab
Age (years)	n	48	48	383	387
	Median (range)	66.0 (41-86)	68.5 (52-85)	64 (20-85)	65 (36-82)
Sex					
	Female	n (%)	25 (52.1)	179 (46.7)	157 (40.6)
	Male	n (%)	23 (47.9)	204 (53.3)	230 (59.4)
ECOG					
	0	n (%)	19 (39.6)	160 (41.8)	168 (43.4)
	1	n (%)	29 (60.4)	222 (57.9)	219 (56.6)
OS (months)	Median [95% CI]	10.8 [7.4-15.8]	8.6 [6.9-11.6]	11.1 [10.0-12.1]	9.2 [8.3-10.6]
	HR [95% CI], p-value	0.57 [0.34-0.96], 0.0546	..	0.83 [0.70-0.99], 0.036	..
PFS (months)	Median [95% CI]	7.0 [4.8-11.2]	4.6 [3.5-6.5]	7.4 [6.0-7.7]	5.6 [5.3-5.8]
	HR [95% CI], p-value	0.55 [0.34-0.88], 0.0105	..	0.69 [0.58-0.83], <0.0001	..
DoR (months)	Median [95% CI]	11.2 [7.4-NE]	5.4 [2.0-6.8]	7.3 [5.8-7.6]	5.0 [3.8-5.6]
	HR [95% CI], p-value	0.22 [0.08-0.62], 0.0035	..	0.67 [0.48-0.93], n/a	..

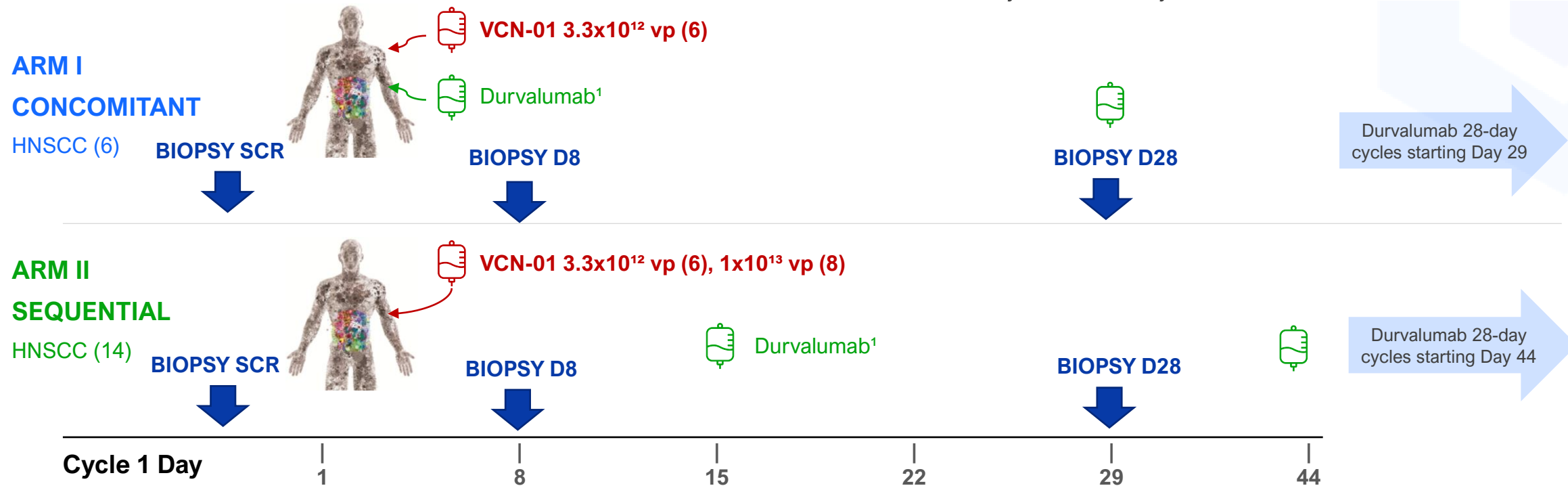
## VCN-01 IN HEAD & NECK CANCER



# VCN-01 IV + ANTI-PD-L1 PHASE 1 TRIAL in HNSCC

## Multicenter, open-label, dose escalation study (NCT03799744)

- ✓ Single IV doses of VCN-01 combined with anti-PD-L1
- ✓ Patients with metastatic squamous cell carcinoma of the head & neck previously **REFRACTORY** to anti-PD(L)1 treatment (R/M HNSCC)
- ✓ Evaluate safety and tolerability, recommended Phase 2 dose



# EXTENDED SURVIVAL with VCN-01+DURVALUMAB

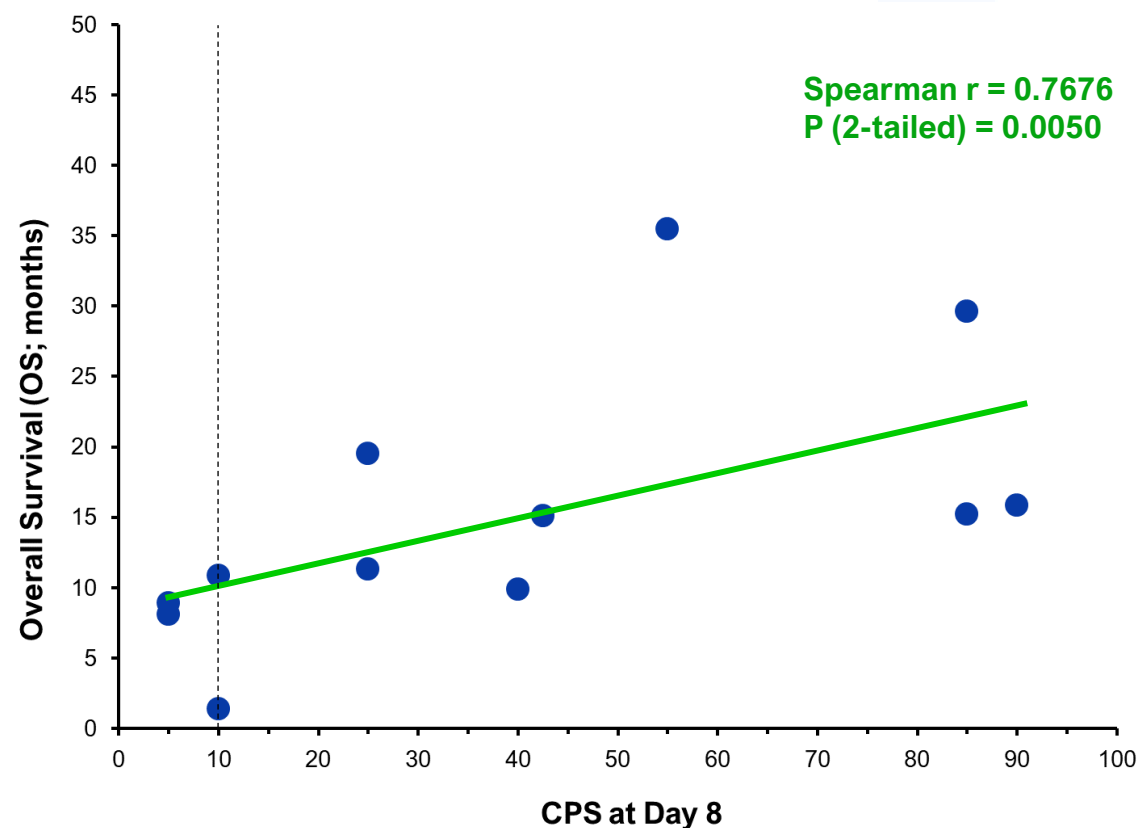
## Survival correlated with PD-L1 upregulation after VCN-01 treatment

- Higher than expected survival (OS) despite previous anti-PD(L)1 failure

Regimen	Median OS (95% CI), mos	
	3.3x10 <sup>12</sup> vp	1.0x10 <sup>13</sup> vp
Concomitant	10.4 (8.9-NE)	..
Sequential	15.5 (15.1-NE)	17.3 (11.3-NE)

- No correlation of survival with baseline tumor PD-L1 expression (CPS) BUT significant correlation of survival with CPS 8-days after VCN-01 treatment

### Overall Survival vs CPS in Biopsies at Day 8





# VCN-01 MAY SENSITIZE PATIENTS TO SUBSEQUENT THERAPY

Patients responded to subsequent chemotherapy after progressing with VCN-01 + durvalumab

ARM	ICI Treatment Progression (Pre-trial)  Median OS post-1st ICI	<u>Current Trial</u>			1st Line after Current Trial	2nd Line after Current Trial
		ORR	Median PFS	Median OS	ORR	ORR
Concomitant Low (3.3E12vp)	21.6 (19.2-NE)	0/6	1.7 (1.6-NE)	10.4 (8.9-NE)	3/5	1/2
Sequential Low (3.3E12vp)	23.9 (16.6-NE)	1/6	3.7 (2.2-NE)	15.5 (15.1-NE)	3/6	1/6
Sequential High (1E13vp)	21.8 (12.9-NE)	0/6	2.1 (1.4-NE)	17.3 (11.3-NE)	2*/5	1/4

\*Complete Responses



# AE PROFILE FOR THE COMBINATION OF VCN-01 AND DURVALUMAB

## Most common AEs related to IV VCN-01 [NCT03799744]

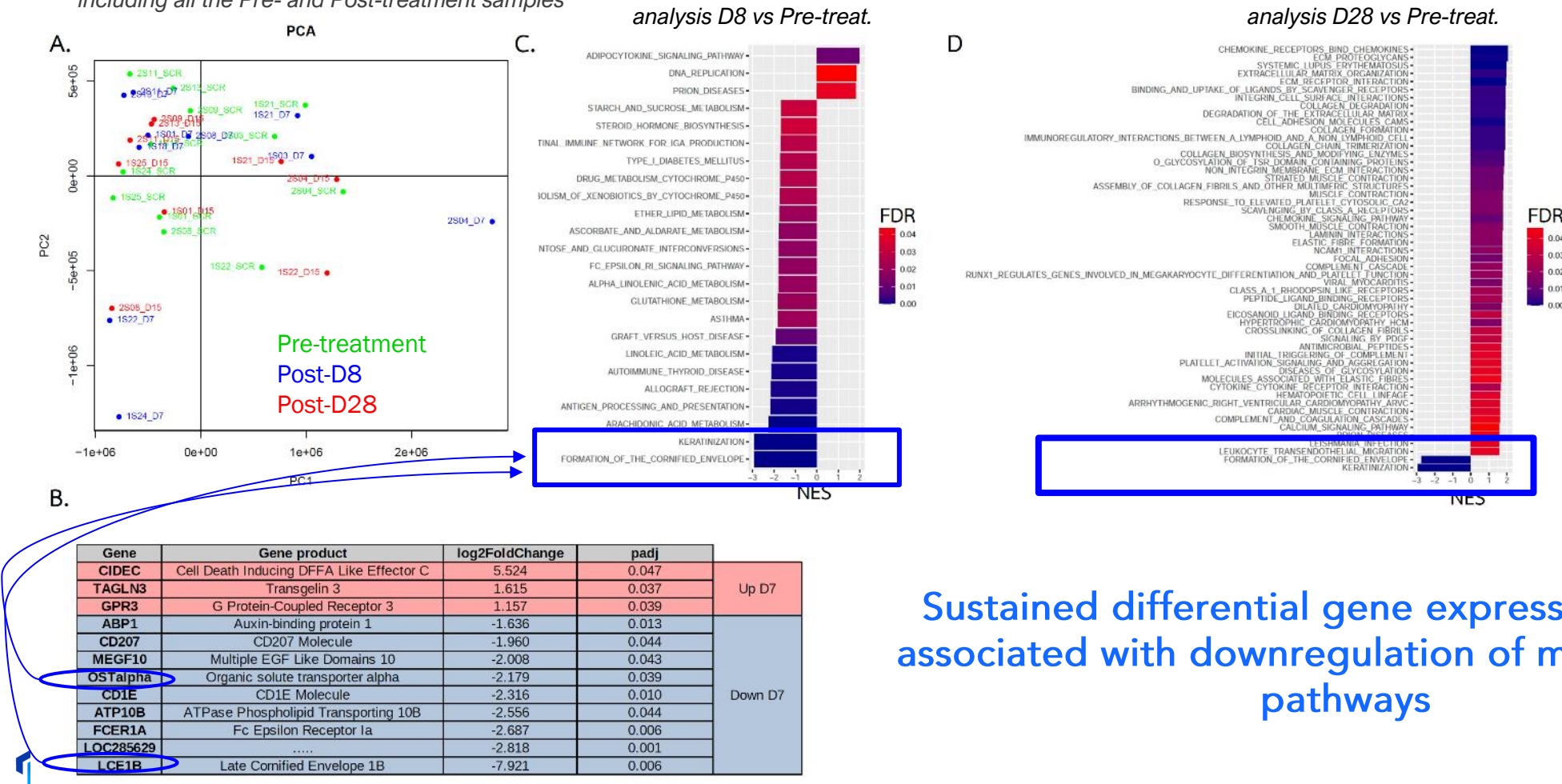
Adverse Reactions	Arm I - Concomitant (Dose 3,3E12 , n=6) <sup>2</sup>		Arm II - Sequential (Dose 3,3E12 , n=6) <sup>3</sup>		Arm II - Sequential (Dose 1E13 , n=8) <sup>3</sup>	
CTCAE Grade	Grade 1-2	Grade ≥3	Grade 1-2	Grade ≥3	Grade 1-2	Grade ≥3
Pyrexia	2 (33,0%)	-	5 (62,5%)	-	3 (50%)	-
Influenza like illness	3 (50,0%)	-	3 (37,5%)	2(25%)	2 (33,3%)	-
Asthenia/Fatigue	2 (33,0%)	-	2 (25%)	1 (12,5%)	4 (66,6%)	-
AST increased	4 (66,7%)	1 (16,6%)	2 (25%)	-	-	2 (33,3%)
ALT increased	3 (50,0%)	1 (16,6%)	1 (12,5%)	-	-	2 (33,3%)
Decreased Appetite	1 (16,6%)	-	3(37,5%)	-	2 (33,3%)	-
Lymphocyte count decreased	1 (16,6%)	-	-	3 (37,5%)	-	-
Myalgia	-	-	3(37,5%)	-	1 (16,6%)	-
Hypotension	-	-	2 (25%)	-	1 (16,6%)	-
Chills	1 (16,6%)	-	1(12,5%)	-	1 (16,6%)	-
Vomiting	1 (16,6%)	-	1(12,5%)	-	1 (16,6%)	-
Anemia	2 (33,0%)	-	1(12,5%)	-	1 (16,6%)	-
Nausea	-	-	1(12,5%)	-	1 (16,6%)	-
Headache	-	-	1(12,5%)	-	1 (16,6%)	-
Erythema	1 (16,6%)	-	1(12,5%)	-	-	-
Guillain-Barre Syndrome	-	1 (16,6%)	-	1 (12,5%)	-	-
Hepatic enzymes increased	-	-	-	1 (12,5%)	-	-
GGT Increased	-	-	-	-	-	1 (12,5%)

# VCN-01 INDUCES TRANSCRIPTOMIC CHANGES in TUMOR MICROENVIRONMENT

## RNAseq Analysis in Clinical Samples from HNSCC Patients [NCT03799744]

Principal Component Analysis<sup>1</sup>  
including all the Pre- and Post-treatment samples

Most significant Reactome and KEGG pathways in GSEA (Gene Set Enrichment Analysis)<sup>1</sup>



Sustained differential gene expression profiles associated with downregulation of matrix-related pathways

# VCN-01 FINDINGS in R/M HNSCC

## Data support VCN-01 MOA and immune enhancing effects

- VCN-01 has an acceptable adverse event profile when administered prior to durvalumab (Imfinzi®)
- VCN-01 reaches tumors, has sustained replication and PH20 expression
- VCN-01 treatment led to downregulation of tumor matrix genes and increased levels of immune markers in tumor biopsies (CD8, PD-L1, IDO)
- VCN-01-treated patients showed increased response to subsequent chemotherapy treatment lines after progressing on this trial

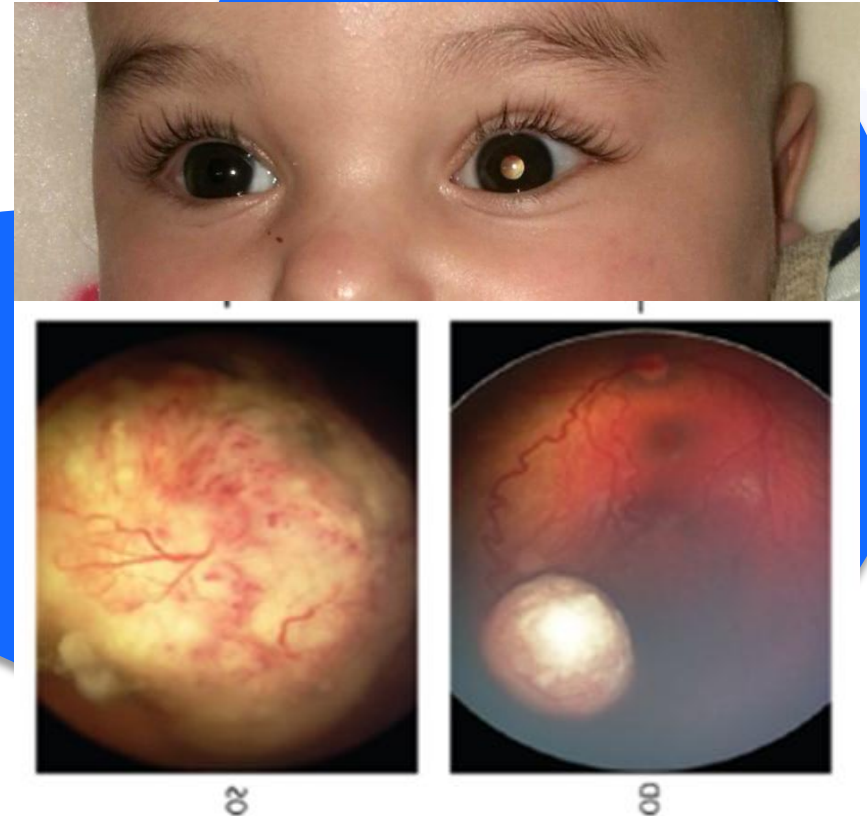


## VCN-01 IN RETINOBLASTOMA



# RETINOBLASTOMA, A RARE PEDIATRIC MALIGNANCY

- Retinoblastoma (Rb) is an orphan indication that accounts for ~2-3% of all childhood cancers<sup>1</sup>
- 200-300 cases each year in the USA, EU<sup>2-4</sup>
- VCN-01 selectivity enables development as an intravitreal treatment for Rb patients
- VCN-01 could be used in combination with chemotherapy to potentially improve outcomes
- VCN-01 could be used as a rescue therapy for patients who fail standard therapy



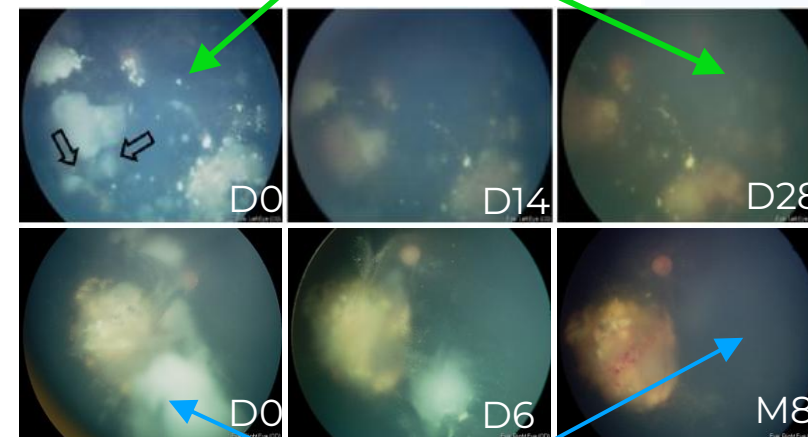
# VCN-01 IN RETINOBLASTOMA

- Single center, open-label, dose escalation study of intravitreal (IVit) VCN-01<sup>1-3</sup>
  - Children aged 1-12 years (n=9)
  - Retinoblastoma that is recurrent or refractory to chemotherapy and for whom enucleation is the best treatment option
  - VCN-01 doses of  $2.0 \times 10^9$  vp per eye (n=1) or  $2.0 \times 10^{10}$  vp per eye (n=8) on days 1 and 15
- Promising antitumor activity and appropriate adverse event profile and tolerability at RP2D
  - Reduction of vitreous seeds in 3 patients of 6 evaluable patients
  - Enucleation avoided in 2 patients; low VCN-01 dose and/or damage from prior chemotherapy meant the eye could not be saved in 4 patients
- Earlier VCN-01 intervention anticipated to have better outcomes

## Promising Results in Patients Treated with High Dose VCN-01

Reduced number and size of tumor vitreous seeds following VCN-01 administration<sup>2</sup>

Pt 2<sup>2</sup>



Pt 3

Complete tumor regression<sup>3</sup>

# INTERIM ADVERSE EVENT DATA FOR INTRAVITREAL VCN-01

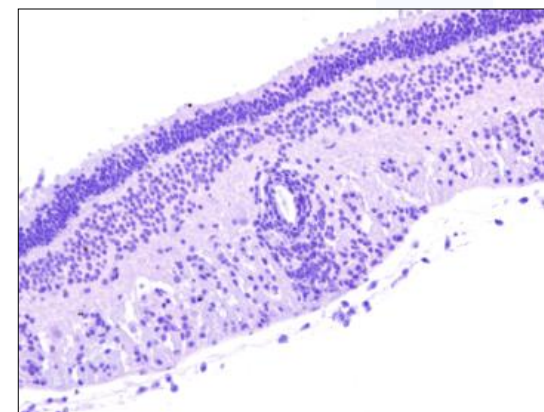
Two Intravitreal VCN-01 Doses of  $2.0 \times 10^9$  or  $2.0 \times 10^{10}$  vp per eye<sup>1</sup>

Adverse Reaction	Pts	All Grades		Grade $\geq 3$	
CTCAE grade	N	n	%	n	%
Uveitis	6	2	33%	2	33%
Eye oedema	6	1	17%	0	0%
Conjunctival hyperemia	6	1	17%	0	0%
Eye inflammation	6	1	17%	0	0%

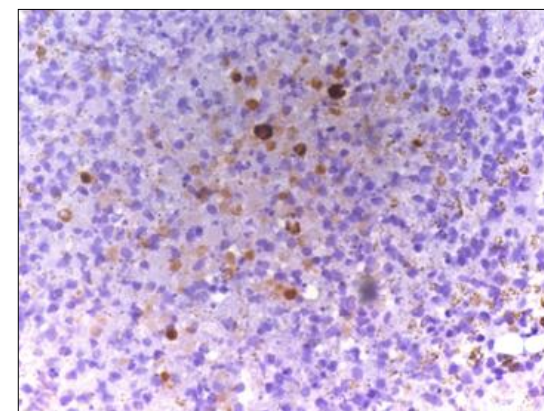
- VCN-01 was reasonably well tolerated after intravitreal administration<sup>2</sup>, although some turbidity and uveitis associated with intravitreal inflammation was observed
- Intravitreal inflammation was managed with local and systemic administration of anti-inflammatory drugs
- VCN-01 induced reversible changes in the electroretinograms but didn't impact visual acuity
- VCN-01 does not replicate in healthy retinal tissue of patients with either somatic or germline Rb mutation<sup>3</sup>

## Selective expression of viral proteins

*Conserved retina*



*Necrotic tumor*





# VCN-01 DEVELOPMENT IN RETINOBLASTOMA

- Phase 1 ISS Completed H1 2024
  - Initial data demonstrate acceptable adverse event profile and one durable complete response
- Developing a clinical protocol for an open-label, multinational study
  - Retinoblastoma patients with vitreous seeds
  - IVit VCN-01 in combination with chemotherapy (no defined SoC)
  - PI Dr. Guillermo Chantada, MD PhD<sup>1</sup>
- Status
  - US and EU Orphan Drug Designation
  - Pre-IND meeting with FDA completed Q4 2023
  - Rare Pediatric Disease Designation (potential eligibility for Priority Review Voucher)



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