



March 2022

# **Investor Presentation**

# Forward Looking Statements

This presentation contains forward-looking statements with the meaning of the Private Securities Litigation Reform Act. These include statements regarding management's expectations, beliefs and intentions regarding, among other things, our product development efforts, business, financial condition, results of operations, strategies, plans and prospects. Forward-looking statements can be identified by the use of forward-looking words such as "believe", "expect", "intend", "plan", "may", "should", "could", "might", "seek", "target", "will", "project", "forecast", "continue" or "anticipate" or their negatives or variations of these words or other comparable words or by the fact that these statements do not relate strictly to historical matters. For example, forward-looking statements are used in this presentation when we discuss Indaptus's future plans and expected timeline of its development pipeline.

Forward-looking statements relate to anticipated or expected events, activities, trends or results as of the date they are made. Because forward-looking statements relate to matters that have not yet occurred, these statements are inherently subject to risks and uncertainties that could cause our actual results to differ materially from any future results expressed or implied by the forward-looking statements. In addition, historical results or conclusions from scientific research and clinical studies do not guarantee that future results would suggest similar conclusions or that historical results referred to herein would be interpreted similarly in light of additional research or otherwise. Many factors could cause actual activities or results to differ materially from the activities and results anticipated in forward-looking statements, including, but not limited to, the following: Indaptus's plans to develop and potentially commercialize its technology; the timing and cost of Indaptus's planned investigational new drug application and any clinical trials; the completion and receiving favorable results in any clinical trials; Indaptus's ability to obtain and maintain regulatory approval of any product candidate; Indaptus's ability to protect and maintain its intellectual property and licensing arrangements; Indaptus's ability to develop, manufacture and commercialize its product candidates; the risk of product liability claims; the availability of reimbursement; the influence of extensive and costly government regulation; and Indaptus's estimates regarding future revenue, expenses, capital requirements and the need for additional financing following the merger. These risks, as well as other risks are discussed in the proxy statement/prospectus that was included in the registration statement on Form S-4 filed with the SEC in connection with the merger.

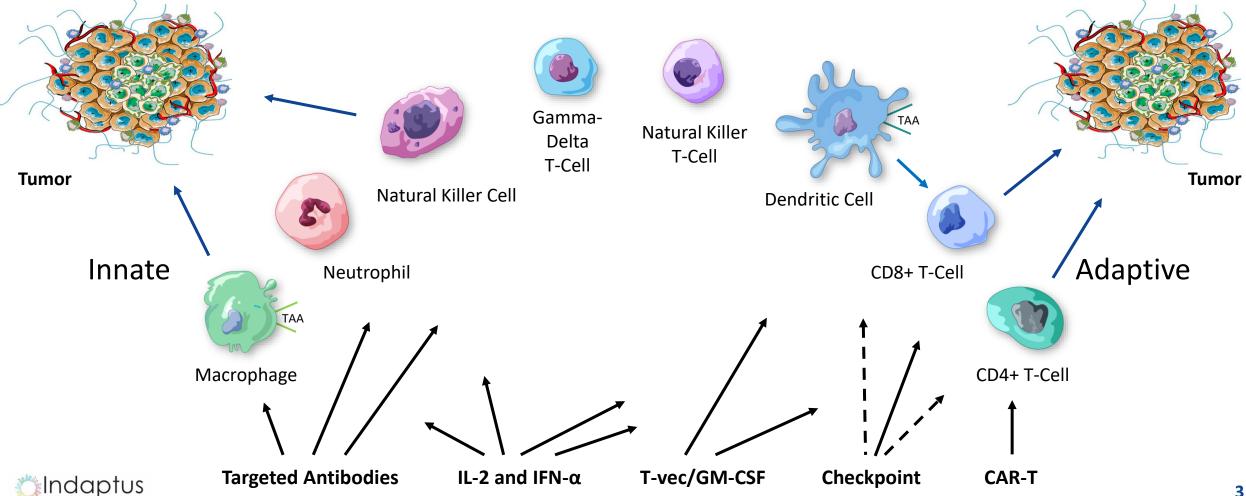
All forward-looking statements speak only as of the date of this presentation and are expressly qualified in their entirety by the cautionary statements included in this presentation. Indaptus does not undertake any obligation to update or revise forward-looking statements to reflect events or circumstances that arise after the date made or to reflect the occurrence of unanticipated events, except as required by applicable law.

The presentation contains information about investigation-stage drug products under development, which have not yet been approved by the FDA for commercial distribution in the United States. All representations in this presentation are based upon investigations in certain clinical and other research, but which accordingly should not be construed as general claims for the safety or efficacy of the products when used by patients.

The presentation is not intended and does not constitute an offer to sell or the solicitation of an offer to buy any securities, nor shall there be any sale of securities in any jurisdiction in which such offer, solicitation or sale would be unlawful prior to the registration or qualification under the securities laws of any jurisdiction. No offering of securities shall be made except by means of a prospectus meeting the requirements of Section 10 of the Securities Act of 1933, as amended.

### **Current Cancer Immunotherapies:** Low Percentage Cures for Most Advanced Cancers

Current approaches activate only one or a few innate or adaptive immune cell types



# Decoy Technology: Improving Cancer Immunotherapy

Shifting approach from continuous single target activation to brief priming of full innate and adaptive cellular pathways

### Assumption

We believe we need innate & adaptive pathway activation in lymphoid organs as well as tumor

- Tumors promote an immunesuppressive environment
- Tumors negatively remodel the entire systemic immune system
- Most steps required for innate and adaptive immune responses take place outside of the tumor

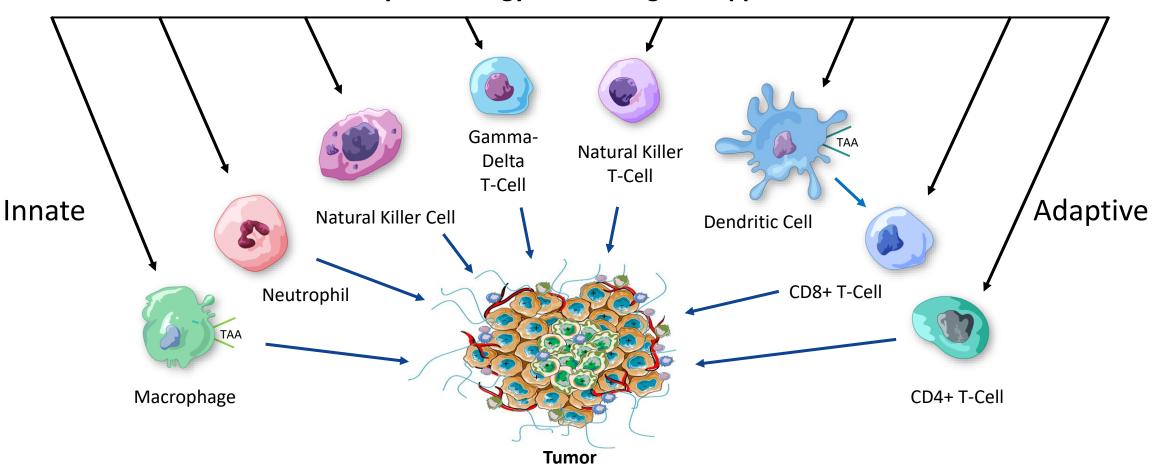
### **Decoy Technology**

Multi-targeted package of i.v. safe immune system activating signals

- Bacteria-based platform
  - Multiple Toll-Like Receptor<del>s</del> (TLR) Agonists
  - NOD-Like Receptors (NLR) Agonists
- TLRs directly and indirectly activate essentially all immune cells (innate + adaptive)
- There is clinical precedent in oncology
- Indaptus pre-clinical data demonstrates potential for safe, systemic administration



### Goal is Activation of Both Innate and Adaptive Cellular Pathways in Multiple Locations Safely



Decoy Technology's multi-targeted approach



# Indaptus has Developed a Novel Approach

### **Decoy Product**

- Start with a single, pure strain of non-pathogenic, Gram-negative bacteria
- Reduce lipopolysaccharide levels by ~90%
- Process therapeutic (e.g. kill the bacteria, stabilize the structure, etc.) for infusion administration
- Product is a frozen suspension
- Chemical modification yields NCE Broad patent coverage: CoM + Methods 4 issued US & 27 issued foreign patents Additional world-wide applications Nominal expiry – 2 families 2033/2039

### **Result and Predictions**

- Decoy therapeutic is significantly less toxic in vivo than untreated bacteria and several live competitor products
- i.v. bacteria are passively targeted to liver, spleen and tumors, and cleared rapidly
- Predict "Goldilocks" effect:
  - Immune activation better than with i.t. dosing:
     Critical activation in spleen and can target primary
     liver cancer and liver metastasis from other tumors
  - Passive targeting and rapid clearance precludes continuous, systemic exposure common to small molecule, antibody and CAR therapies:

Reduced chance of systemic toxicity



# Indaptus Pre Clinical Data – Effective, Safe and Patented

### **Decoy therapeutics exhibit many unique properties**

- Single agent anti-tumor activity + tumor eradicating synergy with 5 different existing therapies
- Reduced toxicity and broad therapeutic index (no increase in toxicity with combinations)
- Safe induction of both innate and adaptive immune pathways (MoA) confirmed
- Innate and adaptive immunological memory leading to rejection of tumor re-challenge
- Efficacy in mouse syngeneic and human tumor xenograft models (CRC, HCC, Pancreatic, NHL)
- GMP batch of drug product produced (Decoy20) stable for ≥6 months at -70°C, -20°C and 5°C
- IND-enabling toxicology with GMP drug product no induction of cytokine release syndrome
- Significant single agent activity in pre-clinical models of HBV and HIV



### Decoy Treatment Does Not Impair Anti-Tumor Cytokine/Chemokine Induction

### Despite being less toxic, Decoy therapeutics induce similar amounts of anti-tumor cytokines and chemokines, uncoupling toxicity from anti-tumor activity

Secretion by Human PBMCs* <u>In Vitro</u>	Untreated <u>Bacteria</u>	Decoy Therapeutic <u>(Decoy10)</u>	Decoy Therapeutic <u>(Decoy20)</u>		
Anti-Tumor <u>Cytokine</u>	•	<u>pg/mL</u> plicate determinations ± %CV sterial dose for each cytokine			
GM-CSF	1,094 ± 22	1,197 ± 2	1,695 ± 23		
IFNγ	175,866 ± 7	47,488 ± 3	55,321 ± 10		
IL-12p70	176 ± 14	528 ± 7	428 ± 37		
ΤΝΓα	49,782 ± 11	77,919 ± 13	99,247 ± 16		

\*Peripheral Blood Mononuclear Cells

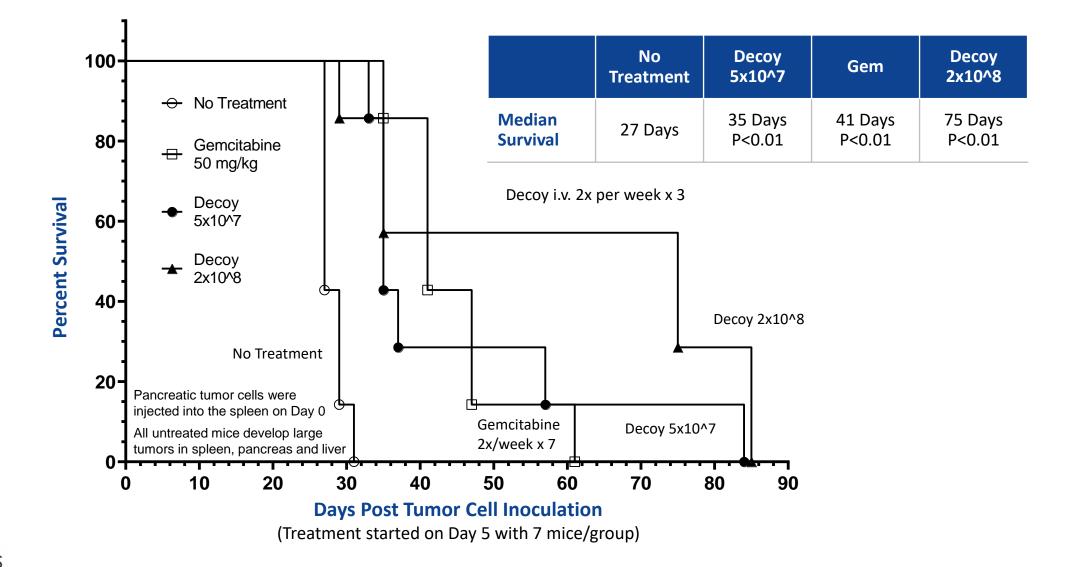
## Decoy therapeutics are more broadly active than mono-specific TLR agonists

Secretion by Human PBMCs <u>In Vitro</u>	<u>CpG</u> (TLR9)	<u>Poly(I:C)</u> ( <u>TLR3)</u>	<u>R848</u> (TLR7/8)	<u>LPS</u> (TLR4)	<u>Decoy10*</u> (TLR2,4,5,9)
<u>Anti-Tumor</u> <u>Cytokine</u>	(triplicate	<u>e full titrati</u>	<u>pg/mL</u> on peak av	verage from	<u>n two exp)</u>
GM-CSF	0	2	136	27	1,246
IFNγ	7	248	61,914	33,293	171,284
IL-12p70	4	15	205	84	375
ΤΝFα	65	334	36,663	24,944	73,069
<b>ΜΙΡ-1</b> α <sup>**</sup>	0	272	17,866	19,278	29,942

\*Decoy therapy tested at doses therapeutically relevant for *in vivo* models \*\*From one experiment

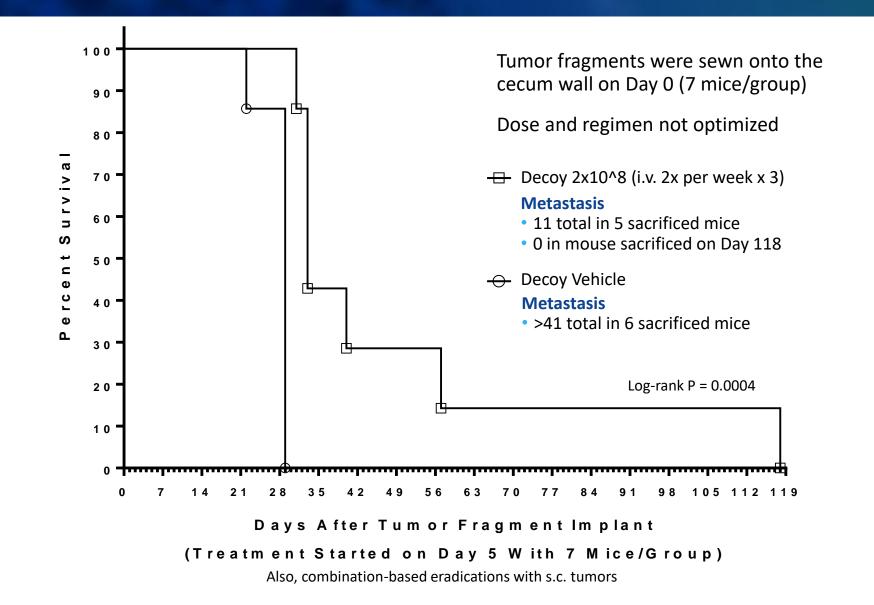


## Single Agent Activity - Metastatic Mouse Pancreatic Carcinoma





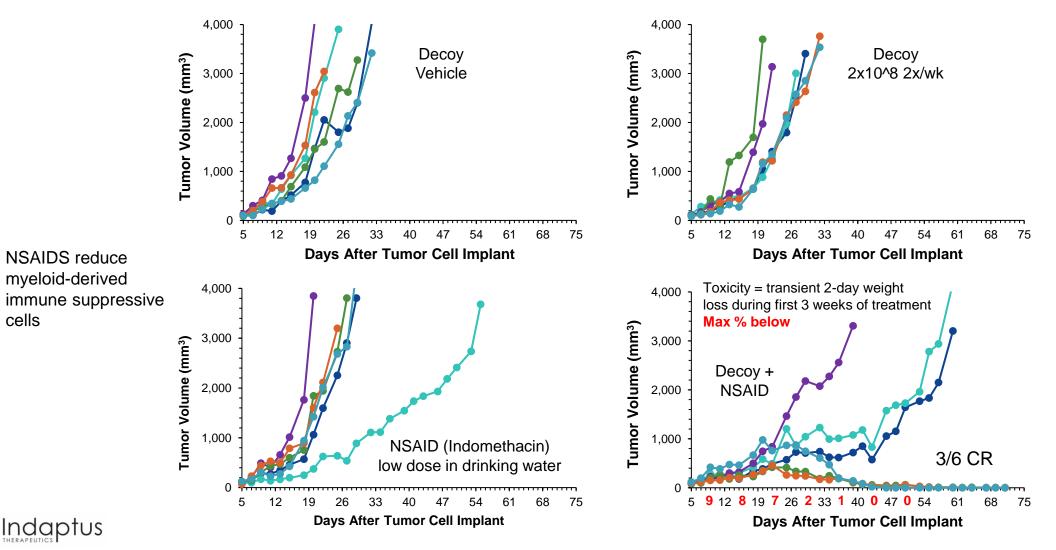
## Single Agent Activity - Orthotopic Mouse Colorectal Carcinoma



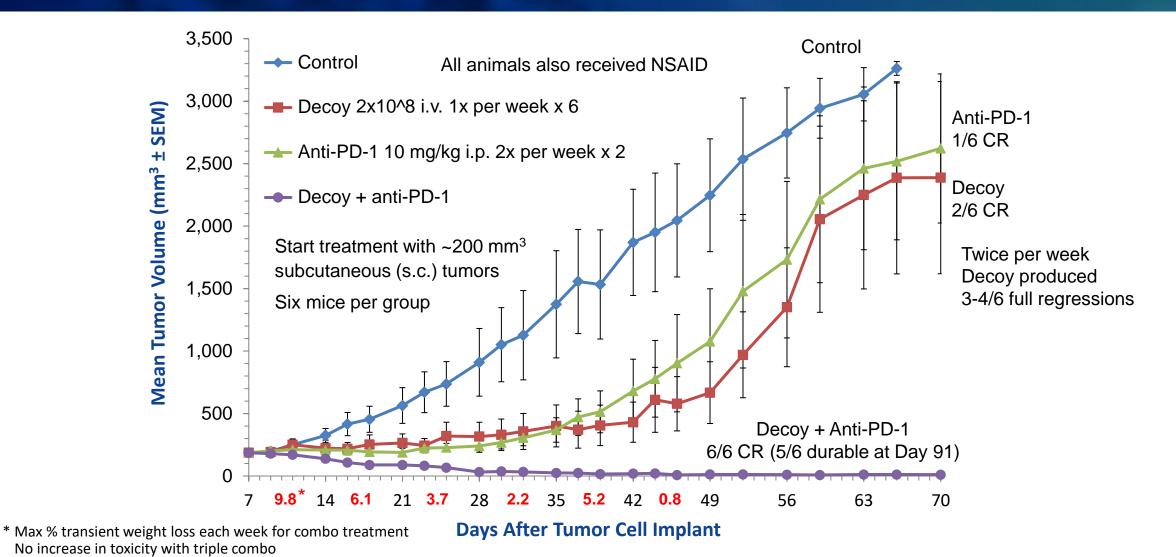
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### Decoy Synergizes With a Non-Steroidal Anti-Inflammatory Drug (NSAID) to Safely Eradicate Subcutaneous Mouse Hepatocellular Carcinomas (HCC)

Treat 6 mice per group with Decoy 2x per week i.v. for 7 weeks / Start treatment at 103 mm<sup>3</sup>

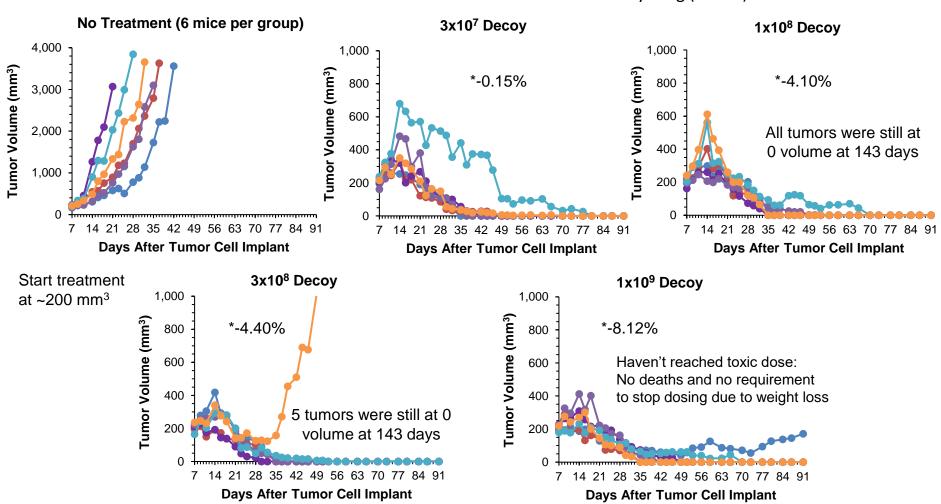


# Combination With Anti-PD-1 Checkpoint Therapy Produces 100% Complete Responses With Hepatocellular Carcinoma



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### Synergistic Eradication of Murine HCC Exhibits a Very Wide Decoy Therapeutic Index (≥33-fold)



All animals also received a non-steroidal anti-inflammatory drug (NSAID)

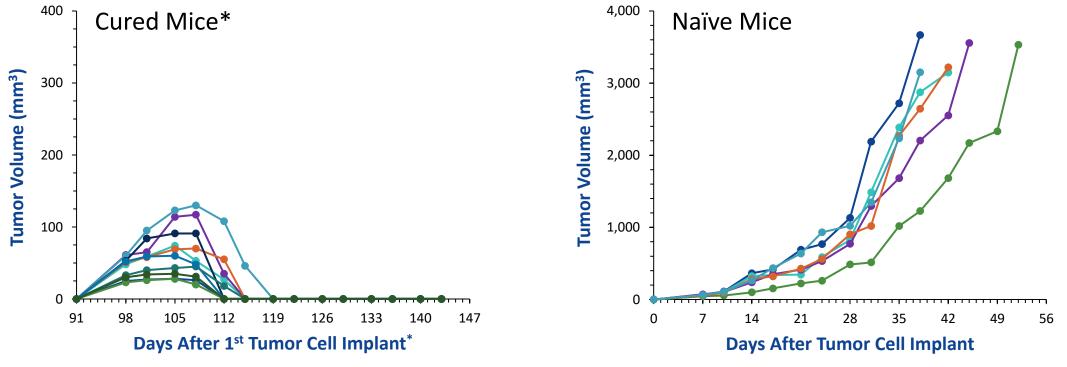


\*Maximum transient body weight loss relative to start of treatment

### Mice Cured by Decoy + NSAID + Anti-PD-1 and Re-Challenged with Fresh HCC Tumor Cells Reject the Tumors (Immunological Memory)



Six Naïve Mice were Challenged with the Same Tumor Cells as the Cured Mice on the Same Day

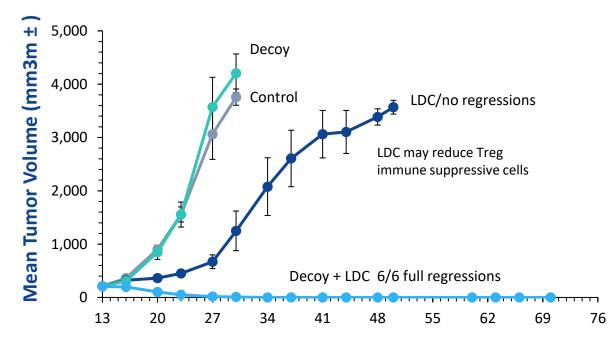


\*All 1<sup>st</sup> challenge tumor sites remained tumor-free



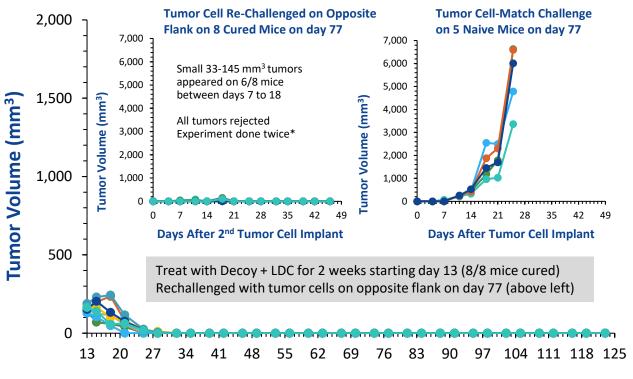
# Decoy Produces Similar Results in Multiple Mouse Models

Decoy Therapeutic Synergizes with Low-Dose Chemotherapy (LDC) to Safely Induce Regression of s.c. Mouse Non-Hodgkin's-Lymphoma (NHL)



**Days After Tumor Cell Implant** 

Mice Cured by Decoy + LDC and Re-Challenged with Fresh NHL Tumor Cells Reject the Tumors (Immunological Memory)

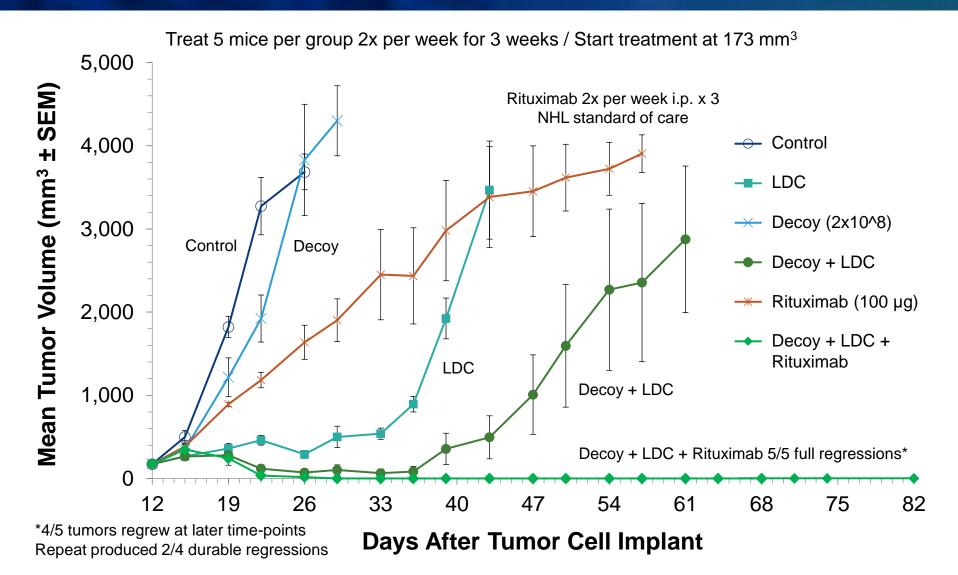


#### Days After 1<sup>st</sup> Tumor Cell Implant

\*Immunological memory also seen with innate-only human tumor xenograft model

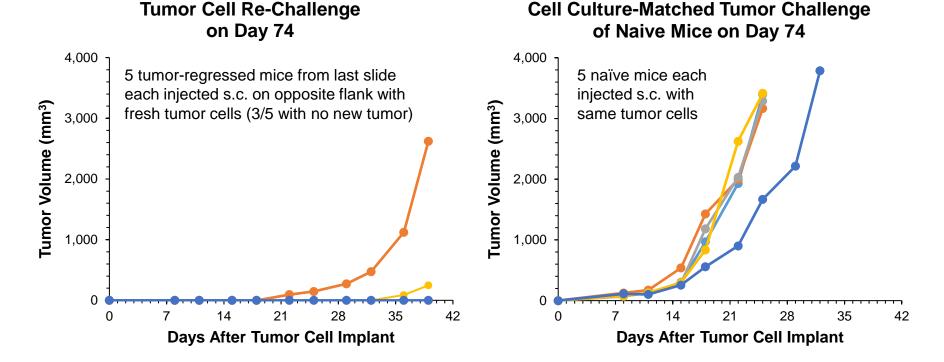


# Decoy Technology Also Regresses Human Tumor Xenografts





### Decoy Technology can Induce Immunological Memory Via the Innate Immune System



- Tumor regression with immunological memory via the innate immune system alone is very rare in preclinical models, but consistent with a multiple danger signal mechanism
- Results suggest that Decoy technology may synergize with other marketed ADCC mechanism-based, targeted antibody therapeutics (~12 on market)



### **Decoy Technology Platform** Potential utility as anti-viral therapy - Hepatitis B Virus (HBV), HIV and Others

- HBV is a chronic liver infection affecting 257 million people world-wide
  - Only 2% treated with current therapies / Major cause of cirrhosis and HCC / 887,000 deaths per year
- Cytokines have strong anti-viral activity, but single, oral TLR agonists have failed in the clinic
- Multi-TLR agonist Decoy therapy is passively targeted to liver and safely induce cytokines
- Standard pre-clinical AAV-HBV mouse model of chronic HBV carried out twice:

Decoy Therapeutic Produces Broader Anti-HBV Activity Than Standard of Care Reverse Transcriptase Inhibitor Entecavir

	Inhibition (including for up to 6 months after cessation of treatment)						
	<b>HBV Replication</b>		HBe Antigen		HBs Antigen	cccDNA-Like Molecule	
	Plasma	Liver	Plasma	Liver	Plasma*	Liver	
Entecavir	$\checkmark$						
Decoy Therapeutic	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	



# Indaptus Clinical Development Plan

	2021	2022	2022	2023	2023	2024	2024	2025	2025	2026
	Q3/4	Q1/2								
Dose Escalation Single Ascending Doses										
Expansion Multiple Doses All Comers Then Focus										
Ph1b Combination Checkpoint / Targeted Abs / Chemo?										

# Target Indications Include 6 of the World's 12 Deadliest Cancers

	12 Deadliest Cancers	World-Wide (Dec	oy Targets)		
		% of Yearly Deaths	% of Yearly Cases		High Unmet Med
1	Lung	18.4	11.6		<b>U</b>
2	Colorectal	9.0	10.0		
3	Stomach	8.2	5.7	_	
4	Liver	8.2	4.7		Percent five-yea
5	Breast	6.6	11.6	- \_	for patients with meta
6	Esophagus	5.3	3.2		
7	Pancreas	4.5	2.5		3% - 17
8	Prostate	3.8	7.1	_ / /	0,0 1,
9	Cervical	3.3	3.2		
10	Leukemia	3.2	2.4	_ /	
11	N-H Lymphoma	2.6	2.8		Source: American Cancer Society
12	Bladder	2.1	3.0		
Dec	oy Indications % of Total	29.7%	26.2%		

dical Need

ar survival astatic disease

7%

Source: CA CANCER J CLIN 2018;68:394-424



# **Board of Directors**

### Leadership experience in new modalities and early development

Roger J. Pomerantz, M.D.	Chairman	ContraFect
Michael J. Newman, Ph.D.	Founder, CSO, Director	Roche SANDOZ UNOVARTIS Decoy Biosystems
Jeffrey Meckler	CEO, Director	COCRYSTAL Q Cypress QPfizer
Anthony J. Maddaluna	Director	americ Expert Solutions.
W. Brad Hayes	Director	LabCorp Builders FirstSource Catheon.
Brian O'Callaghan	Director	Deseva Petra Pharma SONRGY Sangart
Hila Karah	Director	Florafotonica
Mark Gilbert	Director	

# **Experienced Management Team**





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**SANDOZ** Decoy Biosystems

Jeffrey Meckler Chief Executive Officer Michael J. Newman, Ph.D. Founder and Chief Scientific Officer





**Nir Sassi** Chief Financial Officer



Walt A. Linscott Chief Business Officer

**C** C C RYSTAL







**Boyan Litchev, M.D.** Chief Medical Officer



# Indaptus Therapeutics

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With the ability to harness both the body's innate and adaptive immune responses, we believe we are uniquely positioned to revolutionize the treatment of cancer and certain infectious diseases.

$\checkmark$	<b>Broad Platform</b>	<ul> <li>Immunology-based anti-tumor &amp; anti-viral platform with a wide therapeutic index</li> <li>Oncology, HBV, HIV activity</li> </ul>
$\checkmark$	Safety	<ul> <li>Attenuation and passive targeting reduces systemic exposure and toxicity</li> <li>IND-enabling toxicology indicates no induction of cytokine release syndrome</li> </ul>
$\checkmark$	Efficacy	<ul> <li>Synergistic with checkpoint therapy, targeted antibodies or chemotherapy</li> <li>80 to 100% complete responses in multiple mouse and human tumor models</li> </ul>
$\checkmark$	СМС	<ul> <li>Tech transfer &amp; scale up processes completed - GMP material manufactured</li> <li>Clinical product released and stable for ≥6 months under multiple conditions</li> </ul>
$\checkmark$	IP	<ul> <li>Composition of matter (NCE), methods of making and methods of using patents granted</li> <li>Patent estate runs though 2039</li> </ul>
$\checkmark$	Inflection Timeline	<ul> <li>US FDA Pre-IND meeting completed / IND filing anticipated 1H 2022</li> <li>Phase 1 initiation anticipated 2022</li> </ul>

# Thank you