
NanOlogy

Our Approach

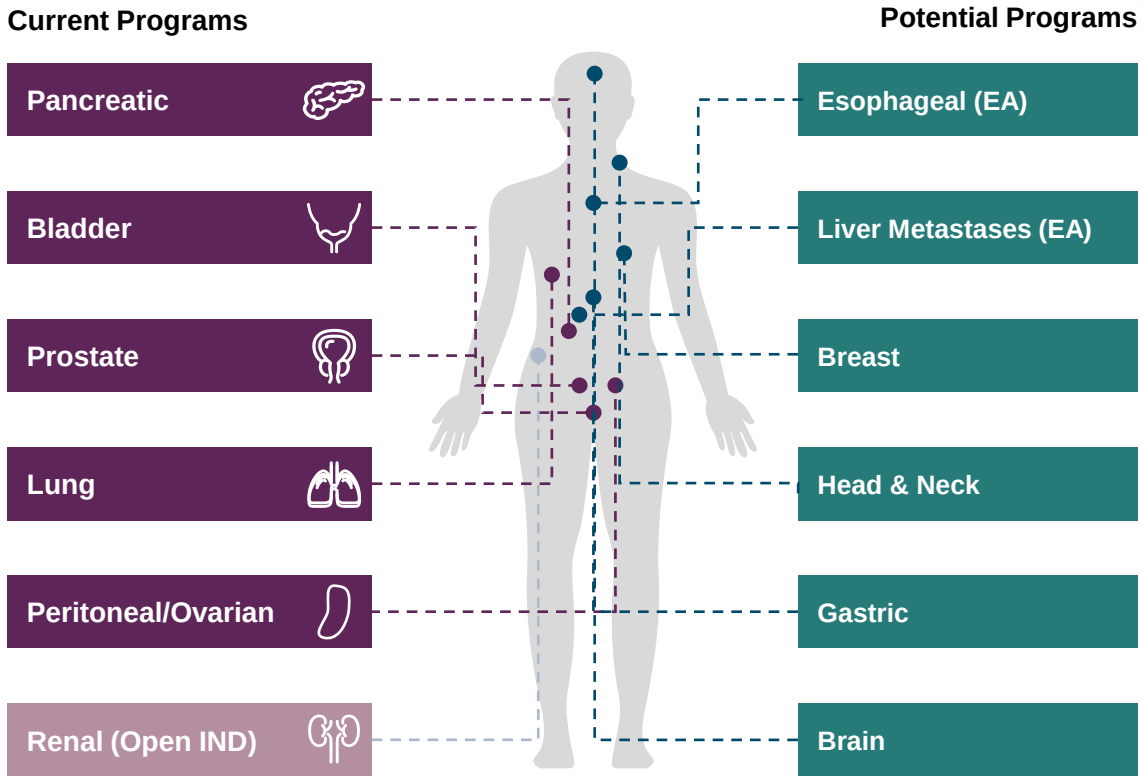
Maximize cancer drug concentration in solid tumors to improve efficacy and minimize off-target systemic toxicity

- ✓ **NanOlogy is advancing a unique particle engineering breakthrough in solid tumor treatment with superior tumor response and significantly reduced toxicity**
- ✓ **Our clinical research is demonstrating:**
  - **Favorable tumor response**
  - **Immunogenic effect**
  - **Minimal toxicity**

Clinical Stage Interventional Oncology Drug Therapy Company

Developing Breakthrough Therapies for Solid Tumors

- Patented large surface area microparticle (LSAM) oncology drug platform engineered for solid tumors
- NanoPac® (LSAM paclitaxel) and NanoDoce® (LSAM docetaxel) in clinical development
- 8 clinical trials / 5 solid tumors
- More than 140 patients treated with promising efficacy data
- Clinical evidence of immunogenic effect
- No confirmed drug-related SAEs
- Tumor-directed therapy with multiple routes of local administration



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Key Issues Remain in Solid Tumor Treatment

Key Issues

Low Response Rate of Immune Checkpoint Inhibitors (ICI)

- Low relative response rate of solid tumors to ICIs and other innovative therapies
- Leading to an explosion of ICI combination trials (1)
- Stacked toxicities
- High cost of combining newer drug therapies

Few Drug Therapies for Solid Tumor Treatment in Local Disease

- Surgery is often treatment of choice but is associated with morbidly and QOL decrease
- Systemic drug use is limited in early disease because of toxicity or lack of bioavailability
- Overall, few drug therapies are approved for local disease

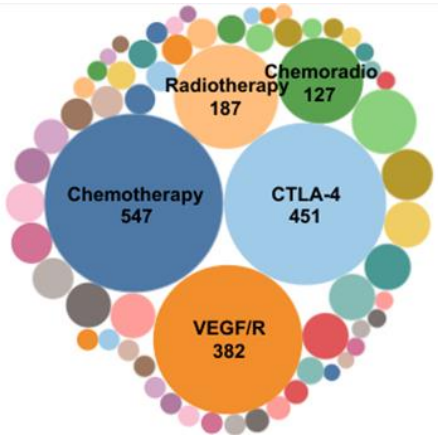
Increasing Focus on Primary Tumors in Metastatic Disease

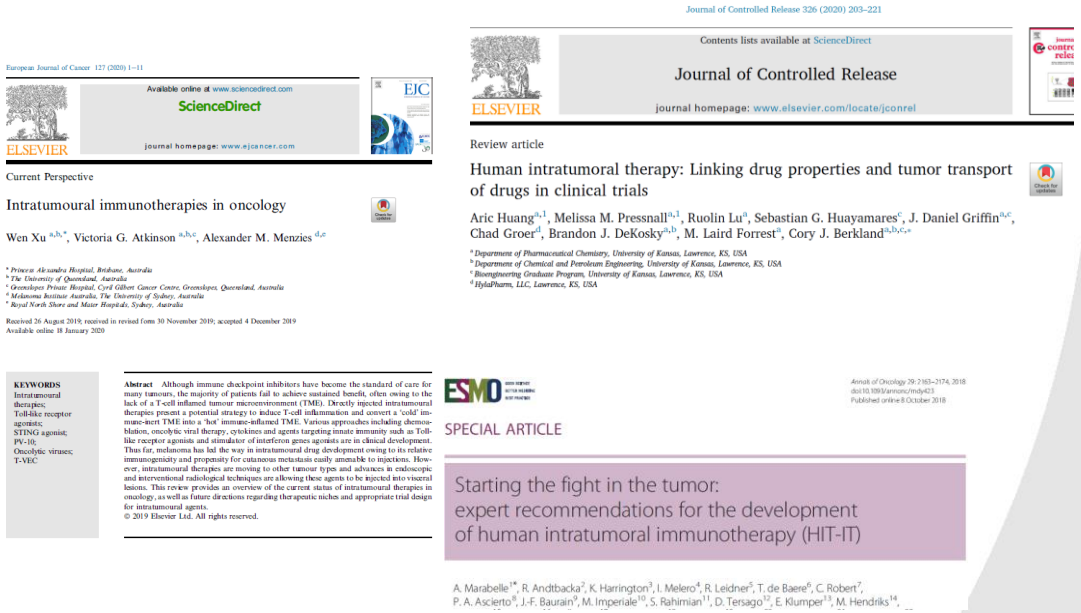
- Research continues to demonstrate the importance of treating the primary and oligometastatic tumors in metastatic disease (2)
- Primary tumor and metastasis-directed therapies like RT have more than doubled since 2000 (3)

Interventional Oncology

- Growing clinical interest in solid tumor directed therapy has led to emergence of interventional oncology over the last several years
- Interventions are mainly limited to devices like RT/ablation
- Few drugs approved for tumor-directed therapy

2900 PD-1/L1 Combination Trials in 2020 Across 253 Targets (1)




European Journal of Cancer 127 (2020) 1–11
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Current Perspective
Intratumoural immunotherapies in oncology
Wen Xu, Victoria G. Atkinson, Alexander M. Menzies
Journal of Controlled Release 326 (2020) 203–221
Contents lists available at ScienceDirect
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journal homepage: www.elsevier.com/locate/jconrel
Review article
Human intratumoral therapy: Linking drug properties and tumor transport of drugs in clinical trials
Aric Huang, Melissa M. Pressnall, Ruolin Lu, Sebastian G. Huayamares, J. Daniel Griffin, Chad Groer, Brandon J. DeKosky, M. Laird Forrest, Cory J. Berkland
SPECIAL ARTICLE
Starting the fight in the tumor: expert recommendations for the development of human intratumoral immunotherapy (HIT-IT)
A. Marabelle, R. Andtbacka, K. Harrington, I. Melero, R. Leidner, T. de Baere, C. Robert, P. A. Ascierto, J.-F. Baurain, M. Imperiale, S. Rahimian, D. Tersago, E. Klumper, M. Hendriks

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1. Upadhava et. al. Nature Reviews Drug Discovery, November 2020; Cancer Research Institute Anna-Maria Kellen Clinical Accelerator
2. Lang P. et.al., Semin Respir Crit Care Med 2020;4 l :369-376
3. Bryant K. et al., Cancer Epidemiol Biomarkers Prev 2017;26:963-970

NanoPac® and NanoDoce® are Designed to Address These Issues

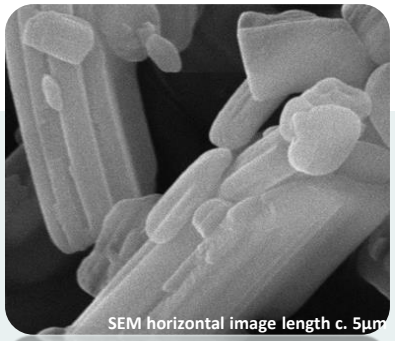
NanOlogy tumor-directed drug therapy uniquely delivers drug into or near solid tumors for drug uptake by the tumor, continuous therapeutic drug release, and minimal systemic exposure to the drug

- **Broad spectrum, tumor agnostic cytotoxicity**
- **High, sustained dose** at the tumor site for several weeks
  - Prolonged **direct tumor cell death**
  - Eliciting **an immunogenic effect** within the tumor microenvironment (TME)
- **Minimal systemic exposure**
  - Allowing for **drug combination strategy** without stacked toxicity
  - Safer, effective **local** disease intervention
- Offering **a high-value tool** to interventional oncologists to target solid tumors

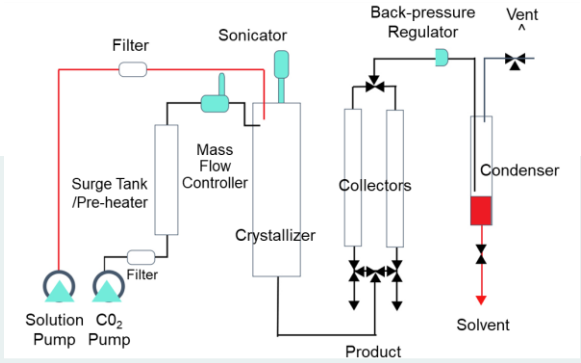
Enabled by a Proprietary SCP Technology Platform

Large Surface Area Microparticle (LSAM) Production

API Crystals

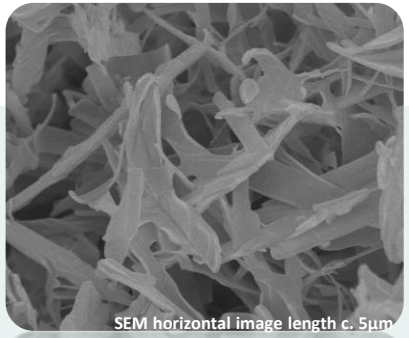


- ✓ Large and bulky crystals
- ✓ Large distribution around mean particle size
- ✓ Poor uniformity of suspensions
- ✓ Poor drug release due to small surface area
- ✓ Limited to dissolution in solvent as a solution for IV delivery



- ✓ API crystals dissolved in organic solvent and injected into precipitation chamber
- ✓ Sonicated into small uniform droplets via sonic probe
- ✓ Solvent stripped away from droplets via supercritical fluid carbon dioxide
- ✓ Stable microparticles of pure drug precipitated and collected on harvesting filters
- ✓ GMP commercial scale
- ✓ Platform for multiple drug classes (TKIs, PARPIs, cisplatin)

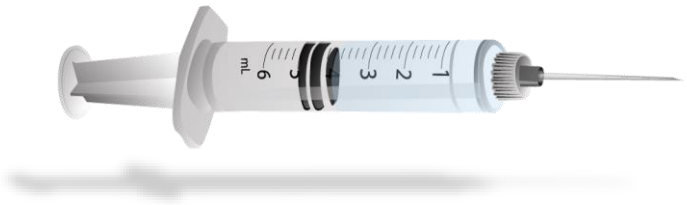
LSAMs



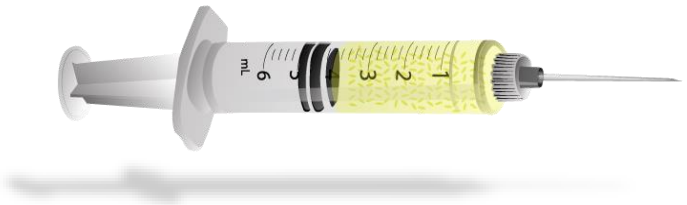
- ✓ Narrow mean particle size distribution
- ✓ Excellent suspension uniformity
- ✓ Microparticles each containing > 1 billion drug molecules suspended in saline-based fluid for local delivery
- ✓ Disproportionately large surface area to particle size ratio allows for:
  - ✓ Particle entrapment
  - ✓ Prolonged therapeutic drug release

LSAMs Offer Much Longer Drug Retention in Solid Tumors

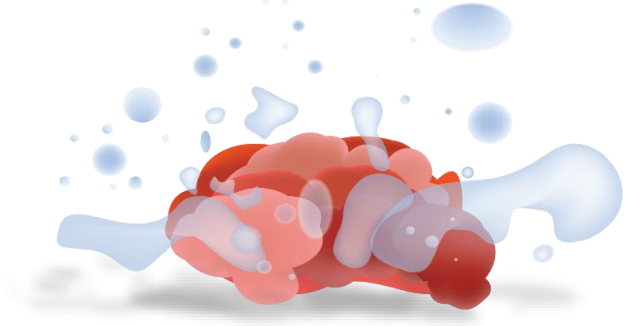
Taxane Solution for Injection



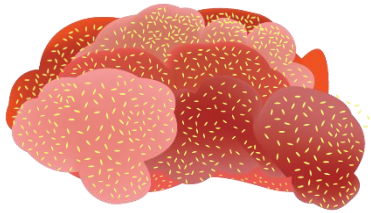
NanoPac or NanoDoce Suspension



Tumor Site

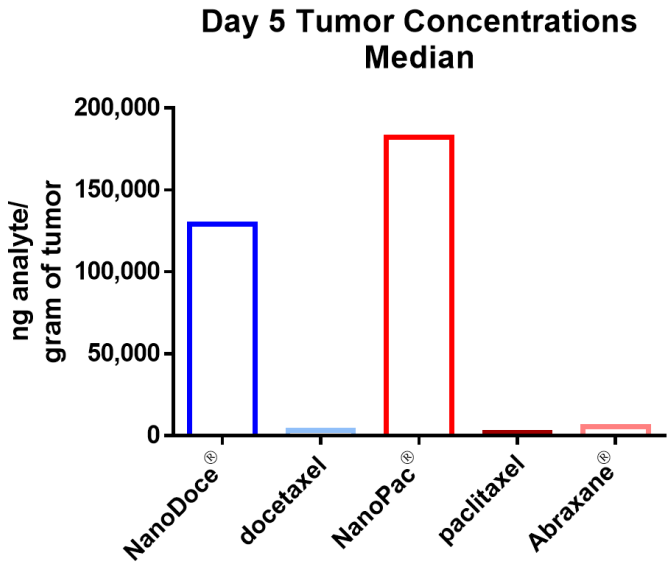


Paclitaxel or docetaxel injection are designed for IV administration and quickly diffuse out of the tumor if injected intratumorally



NanoPac and NanoDoce LSAMs are designed for local administration, and become entrapped in the tumor resulting in sustained therapeutic molecular drug release

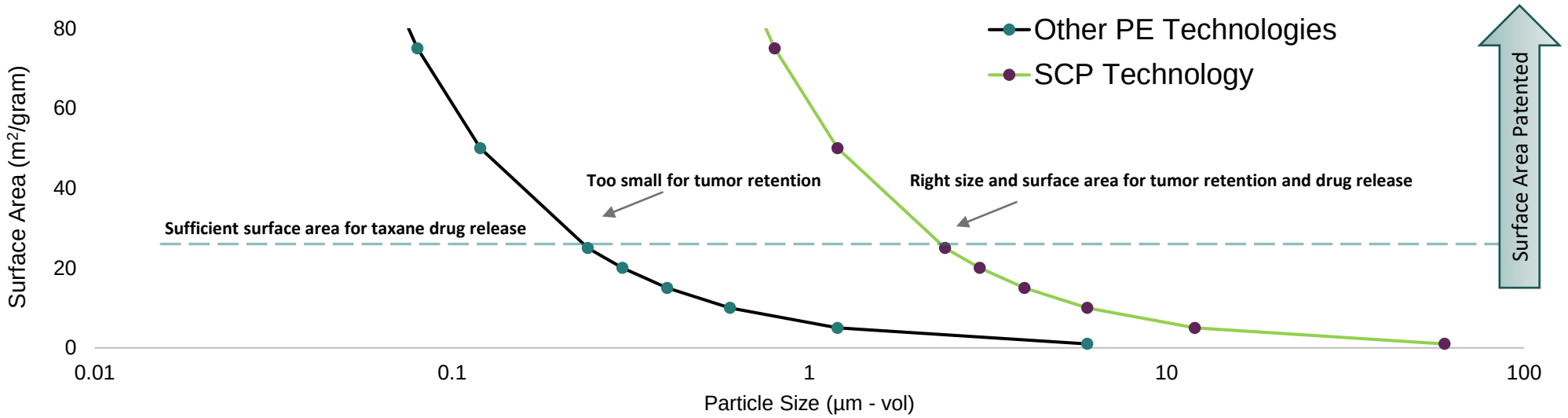
Tumor tissue concentration of NanoPac® and NanoDoce® versus comparators all given intratumorally in mice



Adapted from Verco, S., Maulhardt, H., Baltezor, M. et al. Drug Del Transl Res. (2020). ABRAXANE® is a registered trademark of Abraxis Bioscience LLC, a BMS company.

LSAMs are Formed by a Unique PE Technology

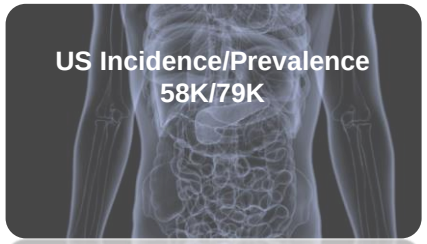
- The SCP technology is different from all other particle engineering (PE) technologies (CESS, RESS, spray drying, milling)
- The SCP technology has a unique ability to engineer **large particles with surface area of a much smaller particle**
- This uniquely **disproportionate surface area to particle size ratio** is optimal for tumor-directed delivery
- The larger size allows for **retention** in the tumor and large surface area for molecular drug **release**
- Taxane **particles with surface area ≥ 18 m^2/g** are protected by a **composition of matter patent** valid until June 2036



Robust Clinical Development Pipeline

Product	Therapeutic Area	Delivery	IND	Phase 1	Phase 2	Phase 3
NanoPac® (LSAM Paclitaxel) for Sterile Suspension	Locally Advanced Pancreatic Adenocarcinoma	Intratumoral				
	Mucinous Cystic Pancreatic Neoplasms	Intracystic				
	Peritoneal Malignancies/Ovarian Cancer	Intraperitoneal				
	Prostate Cancer	Intratumoral				
	Lung Cancer	Intratumoral				
NanoDoce® (LSAM Docetaxel) for Sterile Suspension	High-Risk Non-Muscle Invasive Bladder Cancer	Resection Bed Injection & Intravesical Instillations				
	Muscle Invasive Bladder Cancer	Resection Bed Injection & Intravesical Instillations				
	Renal Cell Carcinoma	Intratumoral				
NanoPac® (LSAM Paclitaxel) for Inhalation	Lung Cancer	Nebulized Inhalation				

Highlights from Most Advanced Trials: LAPC and Bladder



Locally Advanced Pancreatic Cancer (LAPC)

Design

- Single arm, open-label dose-rising single IT injection (EUS-FNI) of NanoPac® in LAPC
- Dose expansion 2 x monthly injection cohort (n=22) and 4 x monthly injection cohort

Highlights

- Favorable tumor response
- 8/14 subjects in neoadjuvant subset restaged from nonsurgical to surgical
- Consistent immunogenic effect
- Well tolerated with no pancreatitis in more than 60 subjects injected with NanoPac
- 4-injection cohort underway (n=5/10) to further evaluate response

Study Objective

- Position NanoPac as integral part of neoadjuvant therapy in borderline resectable or locally advanced pancreatic cancer to improve survival by increasing restaging of nonsurgical candidates to surgical

Bladder Cancer

Design

- Open-label dose-rising single injection/instillation(s) of NanoDoce®
- Two arms:
  - High-risk non-muscle invasive bladder cancer (hrNMIBC) (n=19)
  - Muscle invasive bladder cancer (MIBC) (n=17)

Highlights

- CR @ 3 months in 13/17 (76%) hrNMIBC subjects and 8/13 (62%) maintained CR at 6 months
- CR and bladder intact in 9/14 MIBC subjects evaluable to date at end of 45-day study
- Consistent immunogenic effect
- Well tolerated in all subjects

Study Objective

- Demonstrate a favorable CR rate in high-risk patients to position NanoDoce for pivotal trials across the local disease spectrum

Locally Advanced Pancreatic Cancer

NanoPac® Neoadjuvant Therapy with SOC in LAPC

Importance of Neoadjuvant Therapy

- Surgery offers only significant hope for improved survival
- Neoadjuvant therapy results in significantly improved survival when successful
- Consensus is building on the value of neoadjuvant therapy in BR/LAPC

Clinical Results

- A subset of 8/14 subjects to date restaged from nonsurgical to surgical following addition of NanoPac as part of a neoadjuvant approach (6 have undergone surgery)
  - 5 x R0; 1 x R1
  - 1 x complete pathological response (CPR), 2 > 90% response, and 1 x complete metabolic response (FDG-PET)

Investigator Feedback

- All 14 subjects remained nonsurgical on SOC therapy prior to IT NanoPac
- Neoadjuvant results of 8 restaged subjects represents a series worthy of publication
- CPR is not common
- NanoPac is well tolerated; no pancreatitis to date is an important finding
- Other investigators following neoadjuvant approach in 4-injection cohort to determine if further response is achieved

Phase 2a Data on Neoadjuvant Use of NanoPac (n=14)

Neoadjuvant Therapy for LAPC	Johns Hopkins Retrospective Study [2]	NanOlogy Neoadjuvant Subset [3]
n	415	14
Restaged from Nonsurgical to Surgical	**116 (28%)**	**8 (57%)**
Surgical Resection	**84 (20%)**	**6 (43%) [4]**
R0 Resection	75/84 (89%)	5/6 (83%)
R1 Resection	9/84 (11%)	1/6 (17%)
Time from Diagnosis		
Median OS – Resected	35.3 months	
Median OS – Nonresectable	16.2 months	
Time Post Resection		
Median OS – Resected R0	29.3 months	
Median OS – Resected R1	8.1 months	

Overall Survival (2x injection) [1]		
Month	n	Percent
3M	22/22	100%
6M	20/22	91%
12M [5]	12/22	55%
12M [5] (Resected subjects)	5/6	83%

1. Evaluable subjects at each timepoint to date post 1st injection
2. Ann Surg, 2019; 270(2): 340-347 Johns Hopkins study – cited by NCCN to recommend neoadjuvant therapy in LAPC
3. Subset of subjects (n=14) treated earlier as part of neoadjuvant approach
4. One subject continued chemotherapy and one became metastatic prior to surgery
5. Johns Hopkins OS at 12 months 58% (239/415) from diagnosis; NanOlogy trial from time of enrollment

Neoadjuvant therapy has been demonstrated to significantly increase survival

NCT03077685; FDA IND#132692; NanoPac-2016-05

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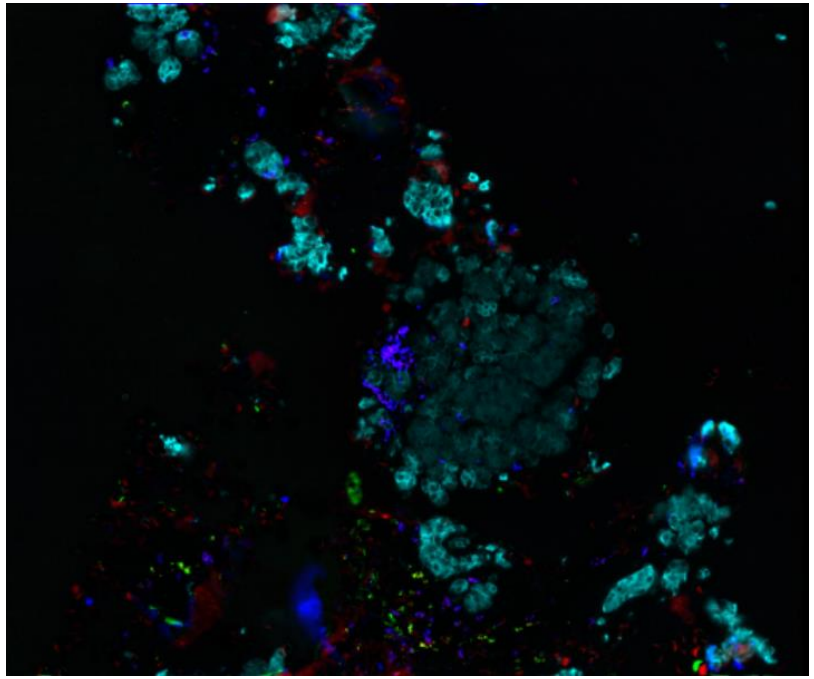
Locally Advanced Pancreatic Cancer

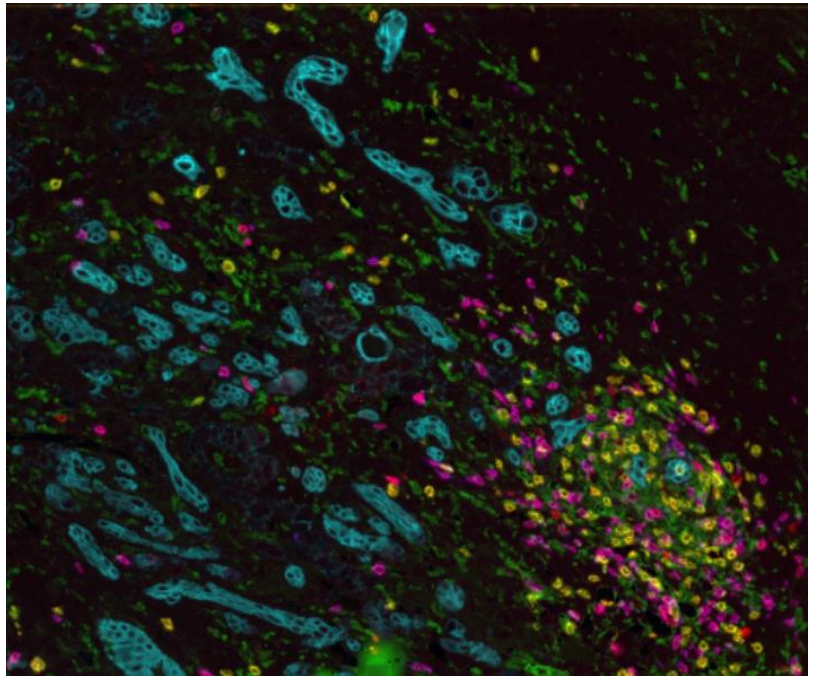
mIF Results: Example of increased immune cell infiltration into TME following treatment

Pre-injection Biopsy



Subject 04001 10858930-02, R000

Surgical Resection



Subject 04001 10858934-03, R007

mIF Image Overlays: **CD3+ CD4+ CD8+ PanCK**

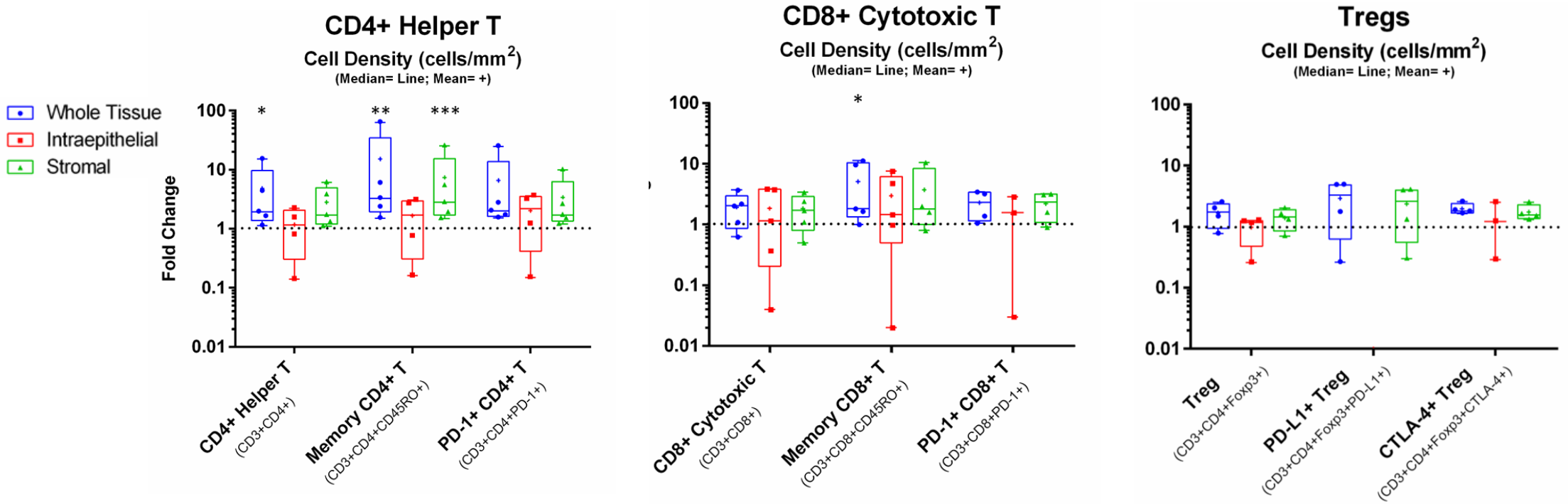
Light Blue = Tumor*; *Yellow = CD4+ Helper T cells*; *Magenta = CD8+ Cytotoxic T Cells

ROI selected based on maximum density of CD8+ T Cells

Locally Advanced Pancreatic Cancer

Consistent Immune Cell Changes from pre-NanoPac injection to resection in 5 LAPC subjects

- Consistent increase in CD4+ Helper T and Memory CD4+ T cells at surgical timepoint vs pre-injection; CD4+ Helper T cell increase concentrated in stroma
- Increase in CD8+ T cells and significant increase in Memory CD8+ T
- No significant increase in Tregs although some suggestion of increase in PD-L1 + Tregs
- Increased T Cell density following NanoPac therapy is consistent with pre-clinical data and mIF results in hrNMIBC subjects treated with NanoDoce®



** = p < 0.05, ** = p < 0.01; *** = p , 0.001; significance by paired t test of per slide cell density for pre-injection vs surgery*

NCT03077685; FDA IND#132692; NanoPac-2016-05

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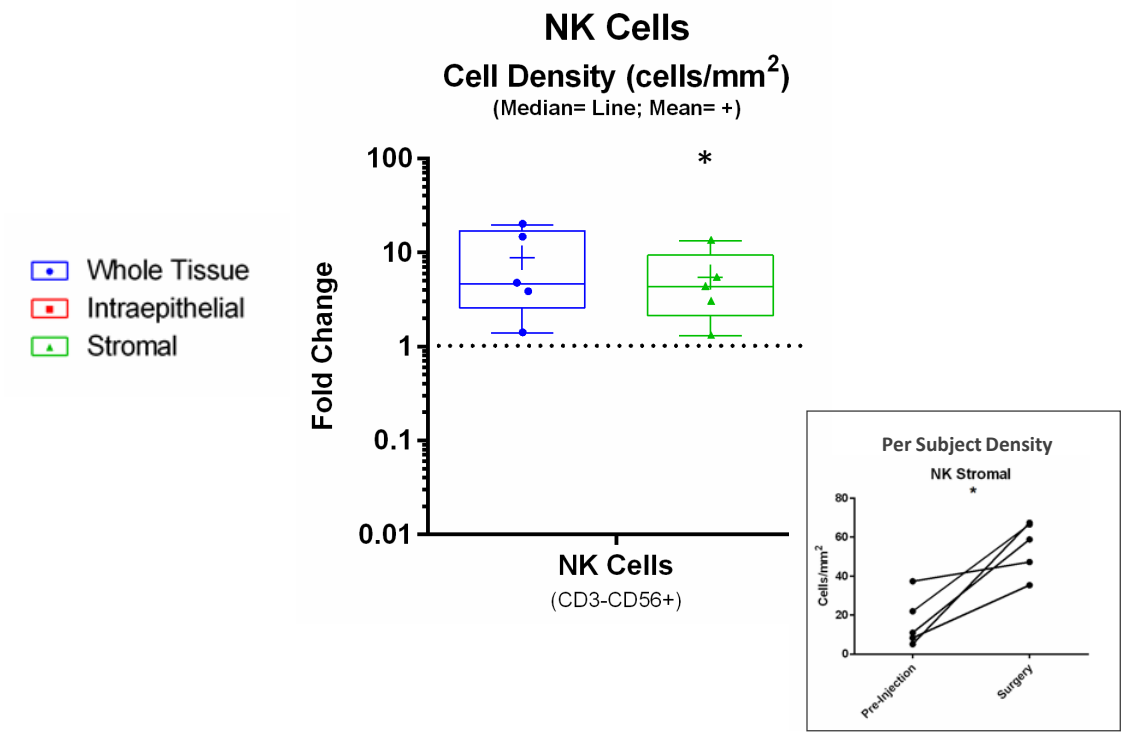
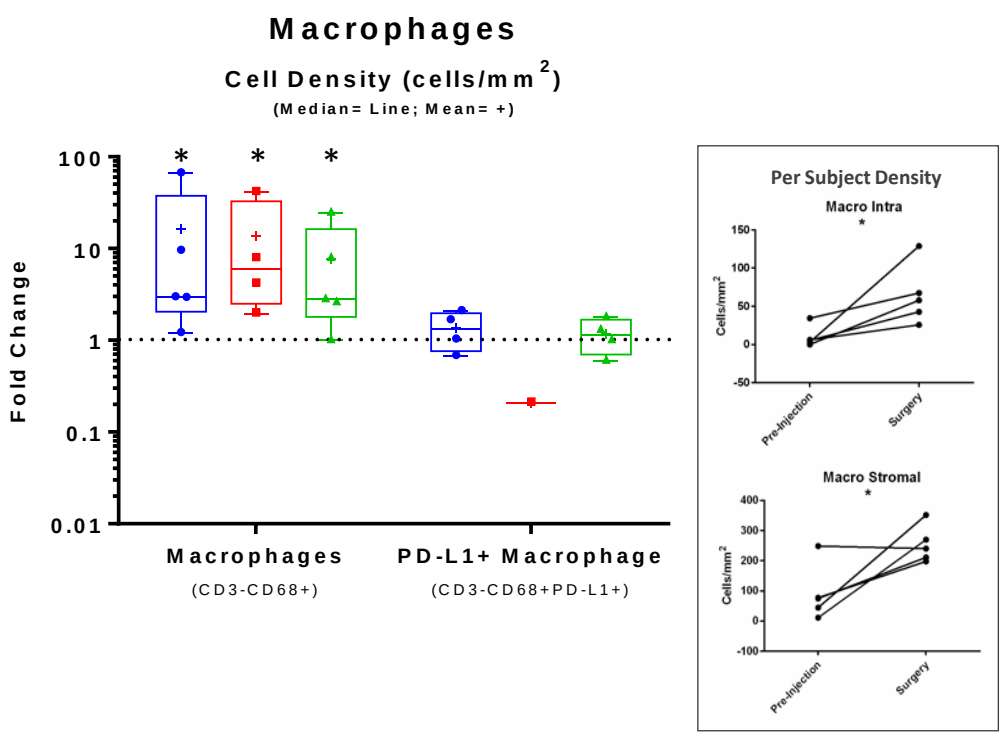
Locally Advanced Pancreatic Cancer

Increases in NK cell density from pre-NanoPac injection to resection in 5 LAPC subjects

- mIF data demonstrates significant increase in NK cells in TME in subjects administered IT NanoPac; consistent with pre-clinical findings and hrNMIBC subjects treated with local NanoDoce
- miF demonstrates significant increase in Macrophages in TME in subjects administered IT NanoPac; PD-L1+ Macrophage remains remains stable pre to post NanoPac therapy



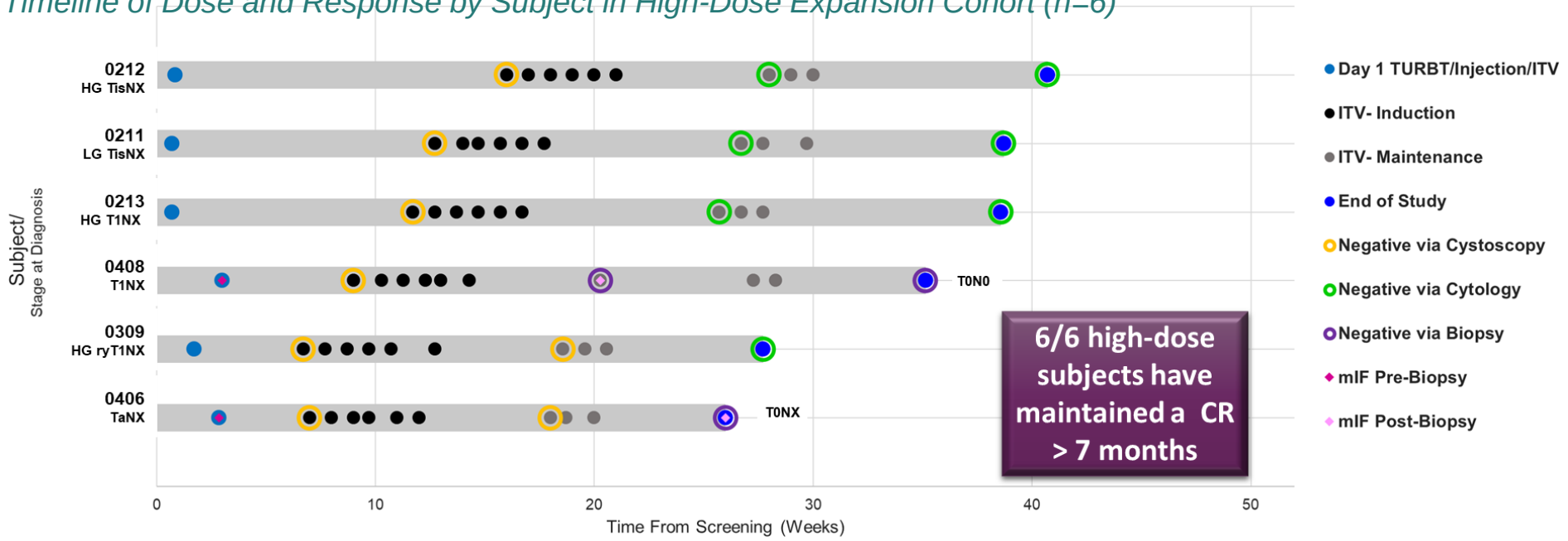


** = p < 0.05, ** = p < 0.01; *** = p , 0.001; significance by paired t test of per slide cell density for pre-injection vs surgery*

High-Risk Non-Muscle Invasive Bladder Cancer

Preliminary Phase 1/2 Data	NanoDoce[1]
Doses administered	1 Direct Injection (3 – 15mg) 10x weekly instillations (50 – 75mg)
3-Month Complete Response	13/17 (76%) 8/10 (80%)
6-Month Complete Response	8/13 CR @ 3-month (62%) 8/17 total subjects (47%)

Timeline of Dose and Response by Subject in High-Dose Expansion Cohort (n=6)



NCT03636256; FDA IND#137404; NanoDoce-2017-02; Preliminary data as oh May 2021

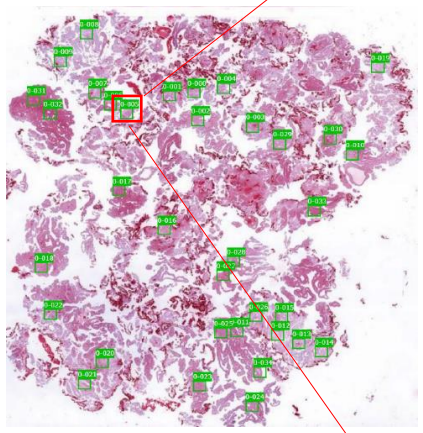
NanOlogy

High-Risk Non-Muscle Invasive Bladder Cancer

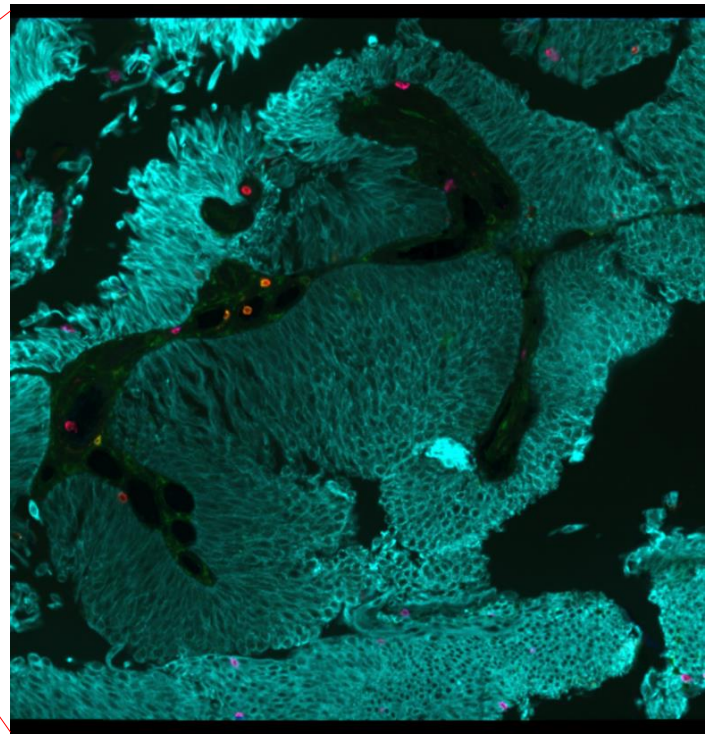
Immune characterization in hrNMIBC subject 0406 without recurrence at 6 months

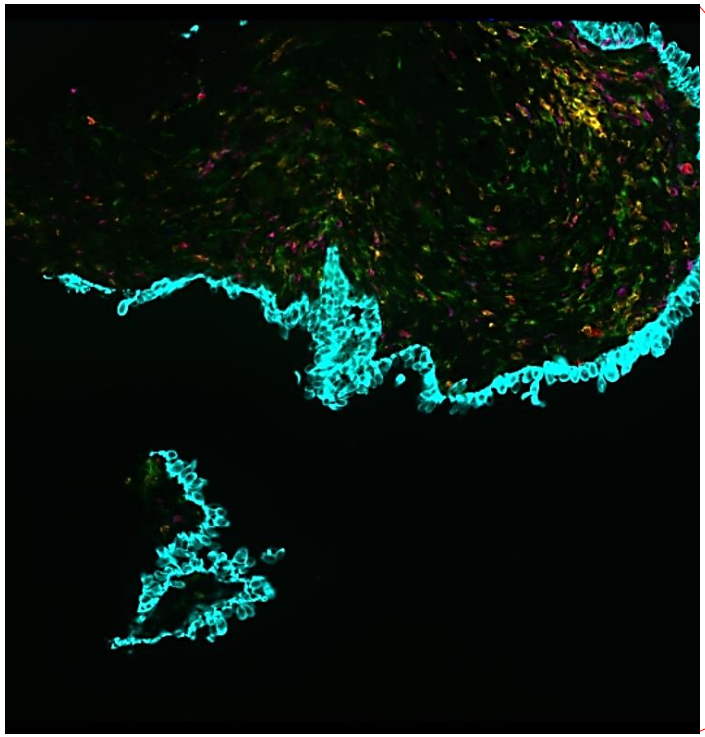
TURBT Sample Pre-NanoDoce

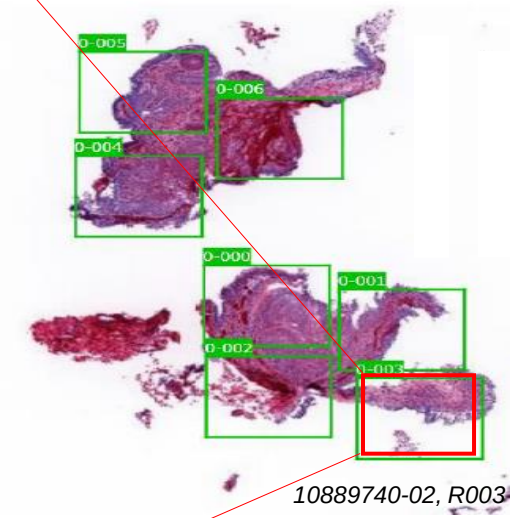
EOT Biopsy Sample



10889737-02, R005







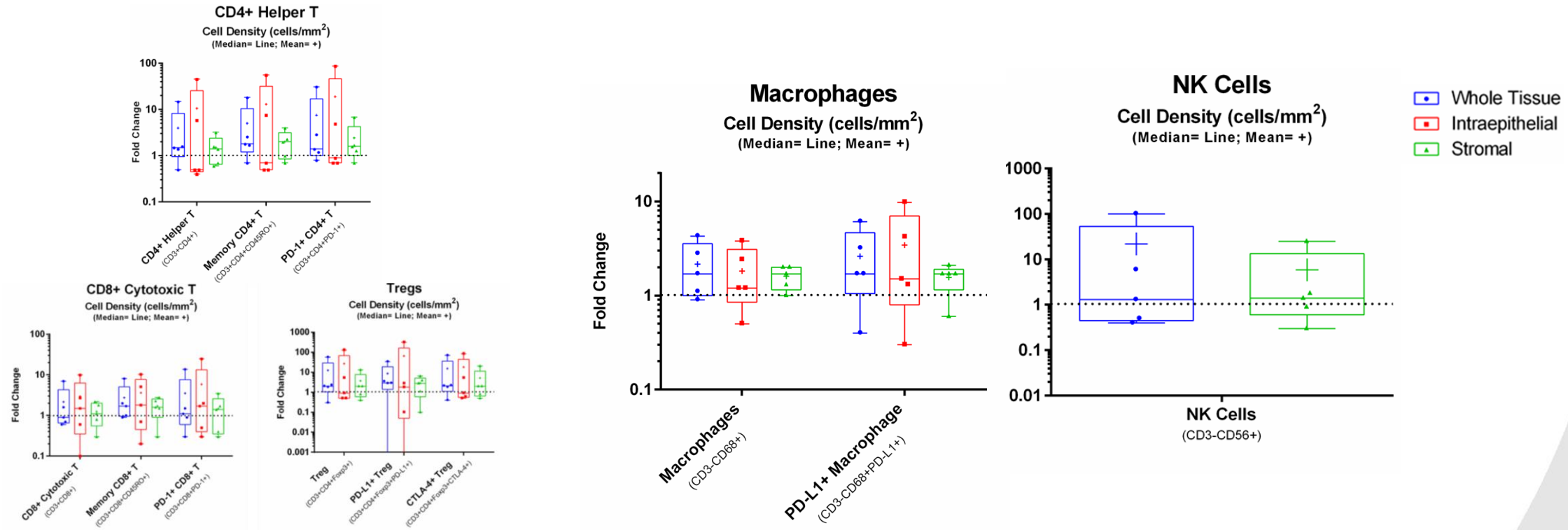
10889740-02, R003

mIF Image (0.2X) Overlays : **CD3+ CD4+ CD8+ PanCK**
Regions of Interest selected based on similar cell density
Light Blue = Tumor; Yellow = CD4+ Helper T cells; Magenta = CD8+ Cytotoxic T Cells

High-Risk Non-Muscle Invasive Bladder Cancer

Changes in immune cell density in NMIBC Subjects

- Across 5 NMIBC subjects:
  - Increased density of T Cells pre to post-NanoDoce treatment
  - Consistent increased density of macrophages (including PD-L1+) (5/5 increased)
  - 3/5 subjects show increase in NK Cell density in TME
  - Variable density of MDSC cells with majority of subjects having decreased MDSC density (3/5 decreased; *data not shown*)



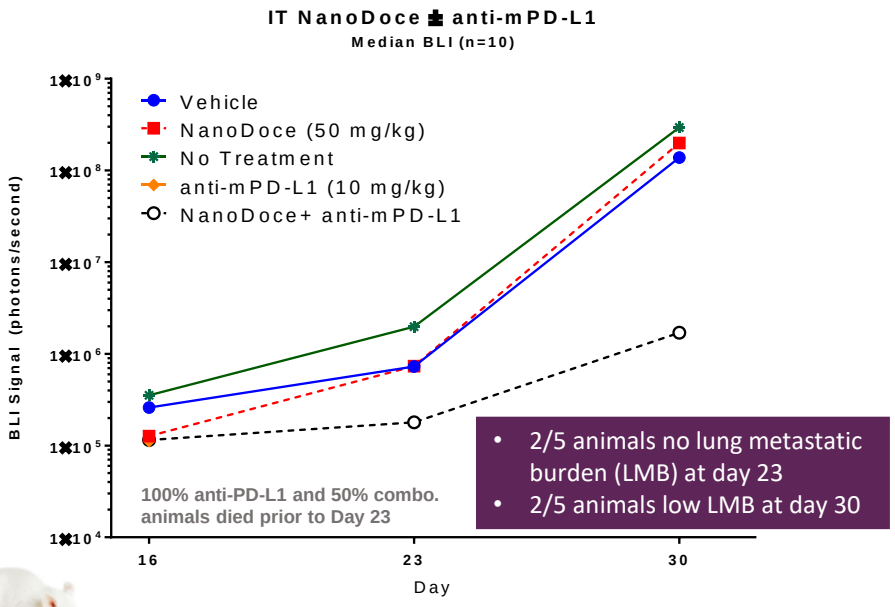
NCT03077685; FDA IND#132692; NanoDoce-2017-02

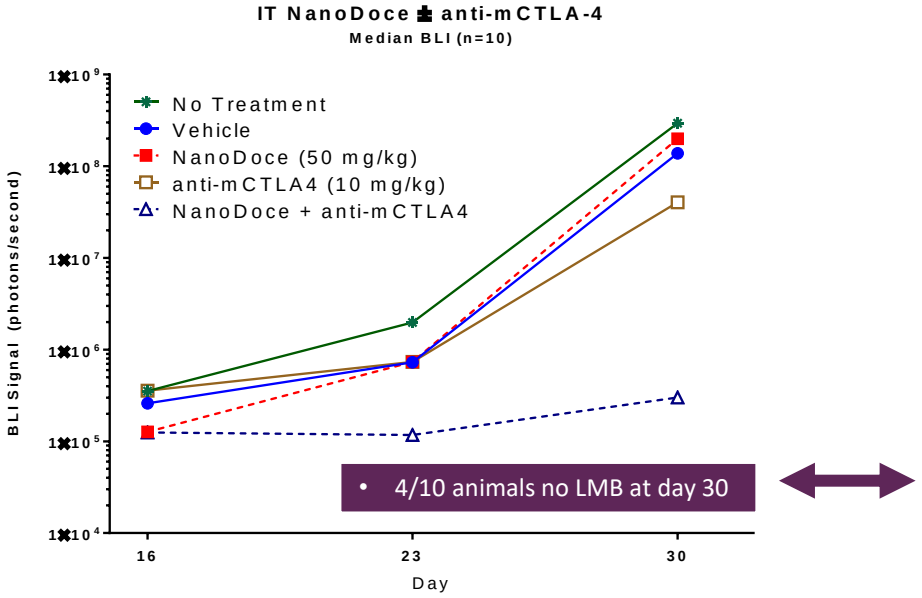
NanOlogy

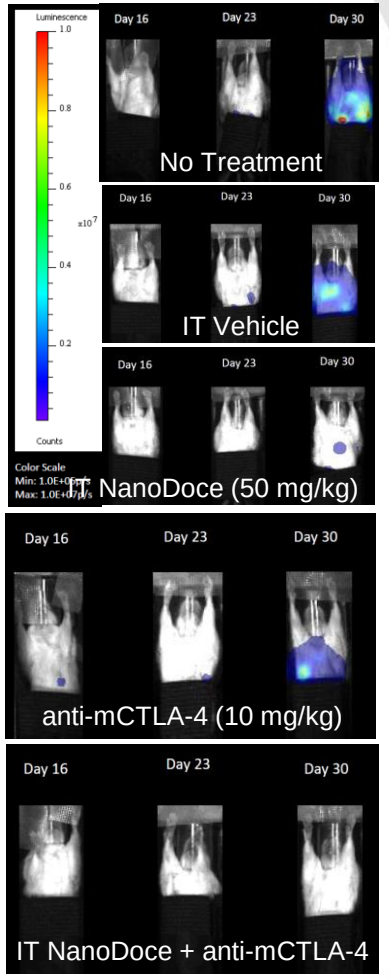
Immune Checkpoint Inhibitor Synergy with NanoDoce®

Preclinical Combinatorial Study in 4T1 (luc) Metastatic Breast Cancer Orthotopic Model

- Anti-CTLA-4 + IT NanoDoce – confirmed synergy
- Anti-PD-L1 + IT NanoDoce – possible synergy
- Anti-PD-1 was not active as monotreatment or in combination in this model
- Similar directional immune cell changes in all groups







NanOlogy Immune Research

Combining NanoPac® and NanoDoce® with ICIs to Increase Solid Tumor Response

Opportunity

- In preclinical studies:
  - NanoPac and NanoDoce tumoricidal and immune response tended to be superior to IV comparators
  - NanoDoce demonstrated immune checkpoint inhibitor (ICI) synergy in a syngeneic model of metastatic disease
- ICI combination trials continue to increase with the goal of **increasing solid tumor response** in advanced disease in combination with **chemotherapy, targeted therapies**, or **RT** leading to potential problems:
  - Additive systemic toxicities
  - High treatment costs particularly with newer therapies
  - Immune suppression
  - Structural change in tumor-specific antigen (RT)
- **NanOlogy investigational drugs have the potential to be a superior companion with ICI therapy**

Key Milestones

- Additional Flow Cytometry and/or mIF immune data from pancreas, bladder, prostate, and lung cancer trials
- Immune effect of addition of IT NanoPac therapy in lung cancer patients on ICIs

Encouraging Clinical Data in Other NanOlogy Programs

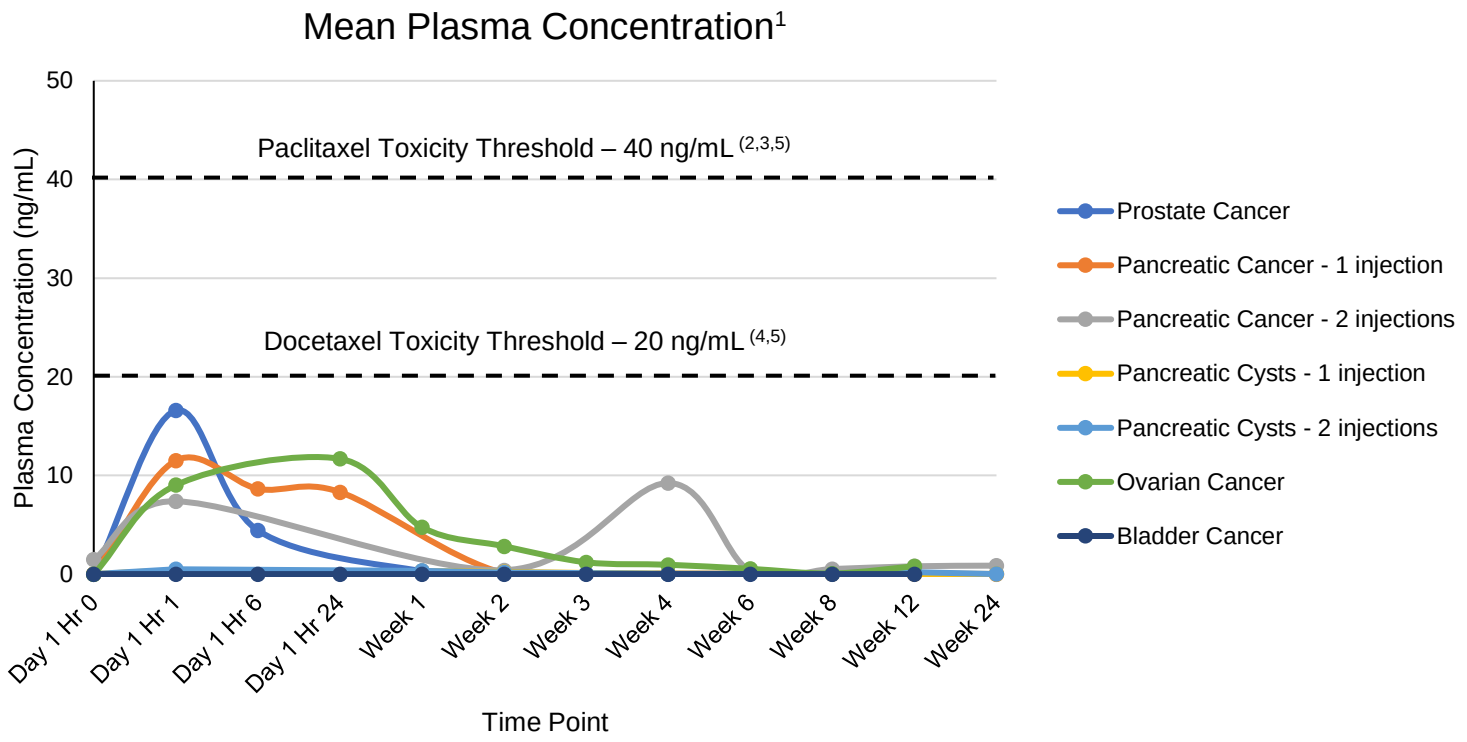
	Indication	Subjects	Trial Phase	Dose	Dose Range	Clinical Data Summary
NanoPac®	Pancreatic Cysts	19	Phase 2a	1 intracystic injection 2 intracystic injections (12 weeks apart)	Volume equal to volume of fluid aspirated from cyst 6, 10, and 15mg/mL	• Cyst volume reduction in 14/19 subjects at 6 months • Evidence of epithelial lining necrosis by DNA analysis or endomicroscopy in selected subjects • PK analysis of cyst fluid at 3 months > 250ng/mL (ULOQ) paclitaxel
	Peritoneal Malignancies	21	Phase 1	1 to 6 intraperitoneal instillations	50 – 275mg/m^2	• 6/21 (29%) subjects (salvage patients) survived > 1 year • Peritoneal fluid concentrations 450-2900 times greater than peak plasma drug concentrations/plasma concentration subtoxic at all timepoints
	Ovarian Cancer	10	Phase 2	1 intraperitoneal instillation	100 – 200mg/m^2	• PFS 60% ≥ 6 months • ORR 50% (CR 20%; PR 30%) • OS 70% > 1 year
	Prostate Cancer	16	Phase 1	1 injection (28 days before prostatectomy)	20% lobe volume (up to 5 mL) 6, 10, and 15mg/mL	• Mean tumor volume reduction 46% • Mean PSA-density decrease 35%
	Prostate Cancer	1/18	Phase 2	Up to 3 monthly injections (1st dose 90 days before prostatectomy)	10% prostate volume (up to 5 mL) 15mg/mL	• First subject enrolled Nov 2020
	Lung Cancer	2/18	Phase 2	Up to 3 monthly injections	20% tumor/node(s) volume (up to 40mL) 15mg/mL	• First subject enrolled April 2021

NanoPac® and NanoDoce® Have a Compelling Safety Profile

	Clinical Trial	Subjects	Events		Systemic SAEs			Local SAEs		
			TEAE	SAE	Definitely Related	Probably Related	Possibly Related	Definitely Related	Probably Related	Possibly Related
NanoPac	Pancreatic Cancer	38	252	34	0	0	0	0	0	4
NanoPac	Pancreatic Cysts	19	99	5	0	0	0	0	1	0
NanoPac	Peritoneal Malignancies	21	332	24	0	0	1	0	0	1
NanoPac	Ovarian Cancer	10	208	13	0	0	0	0	0	7
NanoPac	Prostate Cancer	17	76	0	0	0	0	0	0	0
NanoDoce	Bladder Cancer (NMIBC)	19	121	1	0	0	0	0	0	0
NanoDoce	Bladder Cancer (MIBC)	17	64	3	0	0	0	0	0	0

Plasma Levels from NanOlogy Clinical Trials

Subtoxic plasma drug concentrations at all timepoints demonstrated by clinical PK analysis



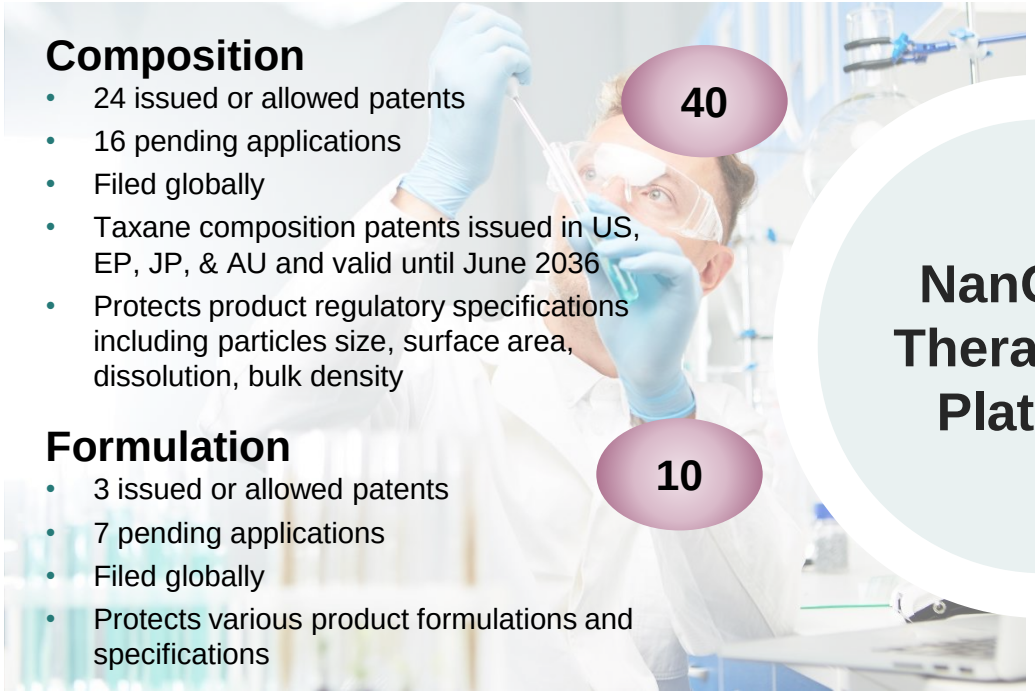
Avoids the systemic toxicities associated with systemic cancer treatments:

- Neutropenia
- Thrombocytopenia
- Peripheral neuropathy
- Alopecia
- Nausea & vomiting
- Colitis & severe diarrhea
- Rash & pruritis
- Hepatotoxicity
- Dose reduction or discontinuation

1. NanoDoce® in bladder cancer only; all others NanoPac®
2. Clin Cancer Res 1999;5:767-774
3. S07-GM-01-2017
4. British Journal of Cancer (2007) 97, 290 – 296
5. LLOQ paclitaxel = 25 pg/mL; LLOQ docetaxel = 10 ng/mL

Growing Global IP Portfolio

IP Protection Like a New Chemical Entity



Composition

40

- 24 issued or allowed patents
- 16 pending applications
- Filed globally
- Taxane composition patents issued in US, EP, JP, & AU and valid until June 2036
- Protects product regulatory specifications including particles size, surface area, dissolution, bulk density

Formulation

10

- 3 issued or allowed patents
- 7 pending applications
- Filed globally
- Protects various product formulations and specifications

NanOlogy Therapeutic Platform

Uses/Indications

136

- 42 issued or allowed patents
- 94 pending applications
- Filed globally
- Protects broad uses: key cancer indications, solid tumors, neoplasia
- Protects routes of administration: IT, IP, inhalation, instillation, topical

Process

73

- 55 issued or allowed patents
- 18 pending applications
- Filed globally
- Protects equipment, assembly, nozzle, methods, precipitation, collection

As of May 2021

Includes

- Combinations with IO
- Kinase Inhibitors
- Orphan designation (ovarian)
- Reducing & Inhibiting Metastasis
- Cancer vaccines/ adoptive cell therapy

Therapeutic Potential Across the Disease Spectrum

Multiple Options for Late Stage Clinical Research are Supported by NanOlogy Clinical Programs

	Pancreas	Bladder	Ovarian/Peritoneal	Prostate	Lung Cancer
US Incidence [1]	**Pancreatic *Cancer*** • **Total:** 58K • **Local: 7**K • **Regional:** 18K • **Metastatic:** 33K **Pancreatic *Cysts*** • **Total:** c. 30K	• **Total:** 81K • **mUC:** 4K • **MIBC:** 19K • **NMIBC:** 58K	• **Ovarian:** 23K • **Other peritoneal:** c. 50K	• **Total:** 192K • **Local:** 147K • **Regional:** 25K • **Metastatic:** 11K • **Unknown: 8**K	***NSCLC*** • **Total:** 196K • **Stage I:** 47K • **Stage II/III:** 69K • **Stage IV:** 80K ***SCLC*** • **Total:** 33K • **Limited:** 10K • **Extensive:** 23K
Initial Indication [2] **(Accessible Patients)**	• Neoadjuvant with systemic SOC in BR/LAPC (22K)	• High risk NMIBC (BCG failure) (30K)	• Adjunct with systemic SOC in peritoneal/ovarian cancer (18K)	• Newly diagnosed intermediate/high risk prostate cancer to delay/prevent prostatectomy (94K)	• Stage II-IV NSCLC (nonoperable) with immune checkpoint inhibitor (106K)
Follow On Indications (Accessible Patients)	• Metastatic pancreatic cancer (33K) • BR-IPMN/MCN nonsurgical candidate (18K)	• MIBC (19K) • Low risk NMIBC (large or multiple tumors) (10K)	• Metastatic or primary tumors confined to the peritoneum (50K)	• Regional/metastatic prostate cancer with immune checkpoint inhibitor (36K)	• Neoadjuvant in Stage I-III NSCLC (operable) (79K)

1. SEER 2020 annual new cases or internal estimates
2. Blue Matter Consulting market research 2019

Clinical Development Strategy

Establish Platform

- ✓ SCP technology
- ✓ Global IP portfolio
- ✓ Solid tumor agnostic
- ✓ Tumor-directed platform
- ✓ NanoPac® and NanoDoce®

Prove Concept

- ✓ Complete clinical trials to generate clinical data across multiple tumors
  - Activity
  - Support ICI combinatorial therapy
  - Safety
- ✓ Support late-stage clinical research
- ✓ Support therapeutic options across the disease spectrum
- ✓ Finalize clinical development strategy

Late-Stage Clinical Research

- Identify partner
- Conduct late-stage clinical trials in prioritized indications

NanOlogy

1. Drug and Technology Platform
2. Potential Across the Disease Spectrum
3. Large Market Opportunity
4. Strong Global Patent Protection
6. Clinical Evidence in Multiple Tumors
7. Additive to SOC without Added Toxicity
8. Expansion Opportunities
9. Commercial Scale GMP Supply