# Purcision™ Microparticle Platform

Engineering Therapeutic Microparticles for Intratumoral Delivery to Enhance Solid Tumor Response Without Added Toxicity

https://nanology.us/

NanOlogy

#### OVERVIEW

The locally-targeted **Purcision™** microparticle platform is designed to enhance solid tumor response

#### Differentiated Microparticle Platform

Commercial scale GMP Purcision technology produces **large surface area microparticles** (LSAMs) of pure drug for multiple drug classes (taxanes, platins, PARPIs, TKIs) and ROAs

#### Established Clinical PoC and Safety

Two intratumoral (IT) investigational drugs (LSAM-PTX, LSAM-DTX) have completed **7 Ph1/2a clinical trials in solid tumors** with excellent tolerability and signs of therapeutic benefit

#### Partnership-Driven Platform Expansion

Ongoing collaboration with a leading pediatric institution funding INDenabling studies of IT LSAM-Cisplatin in a rare pediatric brainstem tumor and opportunity for priority review voucher

## Advancing Towards Ph2b/3 Trials

We are pursuing strategic partners for clinical collaboration and preparing for a capital raise to advance IT LSAM-PTX into Ph2b/3 LAPC and Ph2b resectable NSCLC clinical trials



Global IP portfolio of >130 issued patents in all major geographies

## Strong market protection



**Composition of matter patents** issued/pending on LSAMs valid through **2036** covering all key regulatory specifications



Patent for LSAMs with immune checkpoint inhibitors (CPIs) valid through 2038 offers life cycle extension opportunity for CPIs facing patent cliff

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# New Awakening to the Benefits of Intratumoral Therapy

#### Interventional Interest

#### Historically limited by tumor access:

Clinical interest in intratumoral (IT) therapy has existed for decades but was limited by inability to access solid tumors beyond the periphery

#### Interventional Oncology:

Emerged as a discipline in the last ten years as advancements in *imaging* and *robotically assisted platforms* now allow access to solid tumors anywhere in the body

#### Medical Oncology Interest

#### Importance of primary tumor:

Clinical recognition of the value of treating the primary tumor to prime the immune system to **increase response to systemic SOC** 

#### Targeted therapies fall short:

Targeted therapies (ADCs, RLTs, others) contend with off target toxicities and IP/manufacturing complexities

#### **Recent Industry Interest**

#### **Development pipelines:**

Clinical development of IT drugs has exploded over the last few years to more than 175 clinical trials across multiple drug classes<sup>1</sup>

## Growing investment from pharma:

J&J Interventional Oncology division leads the way with <u>recent</u> <u>expansion of deal</u> with Nanobiotix on Intratumoral NBTXR3 valued at up to \$2.6B

## Intratumoral Therapy

**Intratumoral Research now on forefront:** IT delivered agents are on the forefront of clinical research in both early and late disease because they show significant promise in causing immunogenic tumor cell death to prime the immune system, which increases response to immunotherapy SOC without increasing toxicities

Leader in IT drug development: Established in 2015, Nanology has clinically studied its IT LSAM investigational drugs in over 175 patients across 6 solid tumors and various ROAs establishing safety, signs of therapeutic benefit, and anti-tumor immunomodulation

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SOC: standard of care; ADC: antibody drug conjugate; RLT: radioligand therapy; LSAM: large surface area microparticle; ROA: route of administration

<sup>1.</sup> Intratumoral Injection of Immunotherapeutics: State of the Art and Future Directions. Rahul A. Sheth, Eric Wehrenberg-Klee, Sapna P. Patel, Kristy K. Brock, Nicos Fotiadis, and Thierry de Baère. Radiology 2024 312:1

# NanOlogy **Purcision™** Microparticle Platform

Combination therapy is necessary for solid tumor treatment – but systemic combinations fall short

## Key challenges of systemic combination therapies



#### Off-target toxicities

Systemic delivery leads to toxic exposure in healthy tissues



#### Suboptimal drug exposure

Systemic therapies are typically unable to maintain high levels of drug at the tumor site, reducing efficacy



#### Limited immune engagement

Lower local drug concentrations may not sufficiently trigger antitumor immunity needed for durable response



# Stacked toxicities limit combination therapies

Combinations of systemic therapies increase toxicities including immune suppression, limiting the efficacy of promising combinations

## Our Solution: NanOlogy Purcision™ microparticle platform



#### **Localized Precision**

LSAMs delivered directly to the tumor prime the immune system to increase response to systemic IO SOC without increasing toxicities

#### Enhanced Anti-Tumor Immunomodulation

Exposure to high, continuous drug concentration promotes immunogenic tumor cell death and anti-tumor immunity

#### High, Sustained Drug Exposure in Tumor

Concentrated local drug dose and continuous drug release over time enhances tumor kill

# Purcision enables the full potential of combination therapies

Engineering of otherwise toxic drugs into optimized drug microparticles allows local delivery for combination with systemic therapies without increasing toxicities

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#### **VALUE PROPOSITION**

# The Purcision™ platform is foundationally validated and offers broad clinical and commercial potential

## Platform Technology with Demonstrated MOA



#### Proof-of-platform

**demonstrated**: LSAM agents achieve high local and low systemic drug concentrations post IT delivery



Anti-tumor MOA: Locallydelivered LSAM agents drive tumor cell death in preclinical and clinical studies



Immunomodulatory MOA: IT LSAM-PTX leads to altered immune tumor microenvironment Excellent Safety Profile and Broad Clinical Applicability



 Excellent tolerability across
175 patients in 7 clinical trials
with no confirmed drugrelated SAEs



**Clinical potential** of IT LSAM-PTX has been shown in locally advanced pancreatic cancer



Clinical trials in **6 solid tumors** and **various ROAs** (IT, IP, IMI, IVe) offer multiple clinical development opportunities

# Expansive Market Potential with Favorable Regulatory Path

market potential



The Purcision platform is **suitable for multiple drug classes** with toxicity challenges, expanding



#### 505(b)(2) regulatory pathway

offers reduced development timeline and costs to NDA



Emergence of the interventional oncology field and successful clinical trial execution encourages further development of IT drugs



IMI: Intramural injection; IP: Intraperitoneal; IT: Intratumoral; IVe: Intravesical; LSAM: large surface area microparticles; LSAM-DTX: LSAM-docetaxel; LSAM-PTX: LSAM-paclitaxel; MOA: Mechanism of Action; ROA: Route of Administration; SAE: Serious Adverse Events

# NanOlogy Lead Programs

Product	Initial Indication	Delivery	Feasibility	IND	Phase 1	Phase 2			
LSAM-PTX	Resectable, High-Risk Non-Small Cell Lung Cancer	Intratumoral	Phase 2b protocol	Phase 2b protocol submission to FDA planned 1Q2025					
	Locally Advanced Pancreatic Cancer	Intratumoral	Phase 2b/3 protoc	Phase 2b/3 protocol submitted to FDA in June 2024					
LSAM-Cisplatin	Diffuse Intrinsic Pontine Glioma	Intratumoral	Research Collabora	tion					
NanOlogy	Resectable, High- Risk NSCLC •530K patients per year (Global)	M-paclitaxel	Locally Advanced Pancreatic Cancer ~175K patients per year (Global)		Diffuse Intrin Pontine Glic ~300-600 child diagnosed per (US/EU)	nsic and dren year Opportunity for priority review voucher			

# NanOlogy Platform Expansion Programs

Total market opportunity for all programs including NSCLC and LAPC > 1.5 million patients globally

Product	Therapeutic Area	Delivery	Feasibility	IND	Phase 1	Phase 2
LSAM-PTX	Prostate Cancer	Intratumoral				
	Peritoneal Malignancies / Ovarian Cancer	Intratumoral				
	Mucinous Cystic Pancreatic Neoplasms	Intratumoral				
LSAM-DTX	Non-Muscle Invasive Bladder Cancer	Resection Bed Injection & Intravesical Instillations				
	Muscle Invasive Bladder Cancer	Resection Bed Injection & Intravesical Instillations				
	Renal Cell Carcinoma	Intratumoral			•	
	Prostate Cancer	Intratumoral				
Topical Submicron Particle Paclitaxel	Cutaneous Metastases of Breast Cancer	Topical				
LSAM-PTX for Inhalation	Non-Small Cell Lung Cancer	Nebulized Inhalation				
LSAM-Cisplatin	Solid Tumors	Intratumoral				
LSAM-PARPIs	Solid Tumors	Intratumoral				
LSAM-TKIs	Solid Tumors	Intratumoral				



LSAM: large surface area microparticles; LSAM-DTX: LSAM-docetaxel; LSAM-PTX: LSAM-paclitaxel; LSAM-PARPI: LSAM-PARPI inhibitor; LSAM-TKI: LSAM-tyrosine kinase inhibitor

## Partner With Us

## **Purcision™ Platform**

LSAM investigational drugs have therapeutic potential as single agents or in combination across the cancer disease spectrum

## Grow and Differentiate your Oncology Portfolio

Enhance your portfolio with a **platform technology** that addresses challenges in drug delivery, safety, and combinations

Success across drug classes and indications offers opportunities to optimize existing assets and develop new therapies

## Strong IP Protection and Lifecycle Value

Over 130 issued patents globally, offering robust market protection

The Purcision platform can be applied to NCEs or leveraged to **extend lifecycle** for drugs facing patent cliff

# Streamlined Development

**Partnering Opportunity** 

or broader partnerships

NanOlogy is open to clinical collaboration,

licensing, co-development to expand platform,

## and Commercialization

505(b)(2) regulatory pathway can accelerate development and reduce costs to <\$100M for NDA submission, while maintaining innovator pricing

Commercial scale GMP production and expanding interventional oncology field ensures smooth transition from R&D to commercial



Marc lacobucci Business Development marc.iacobucci@nanology.us

## ⊘ NanOlogy