

Nanomedicines for targeted cancer-specific delivery

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Theranostec Overview



- Focus on precision nanomedicines
 - Improves both therapeutic delivery <u>and</u> tumor penetration
- Combination of diagnostic and therapeutic activities
 - Image-guided diagnosis and surgery improves tumor removal
 - Additional trimodal therapeutic activity eliminates remaining tumor
- Pursuing Head and Neck Cancers as lead indication
- Lead compound TheraPhD shows positive in vivo activity in animal models
- Strong patent protection for nanoparticle technology
- Raised 300k in non-dilutive SBIR funding
- Seeking \$20M for IND-enabling studies and phase I clinical trials



Conventional Chemotherapy





Targeted Nano-therapy

Head and Neck Cancers Are an Increasing Threat THERANOSTEC



- 550,000 new cases every year globally
- 6th most prevalent cancer
- Market valued at \$1.3B, projected to reach **\$2.3B** by 2025
- 90% are Squamous Cell Carcinomas (HNSCC)
 - 2015 5-year survival rate: **62.3%**
 - Survival rate unchanged over 24 years
 - Tumors are difficult to remove completely
 - Tumor recurrence is leading cause of death

Current Standard of Care is Inadequate



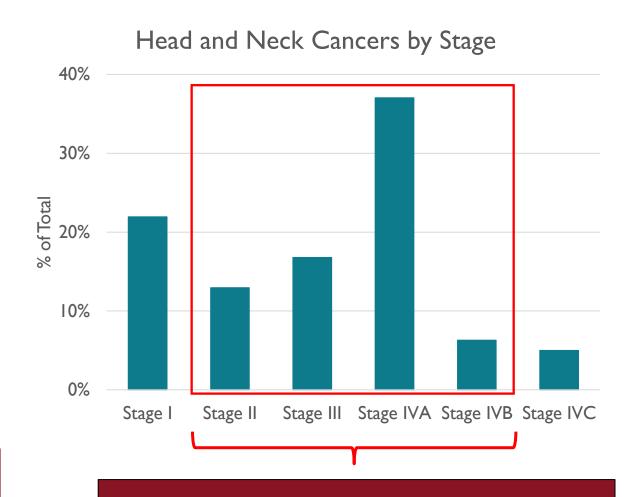
Surgery:

- Difficult to remove due to location
- Doesn't fully remove margin

Chemotherapy:

- Significant off-target activity and sideeffects due to toxicity
- Lack efficacy inefficient at eliminating tumors completely

No current agent has both diagnostic and therapeutic activities

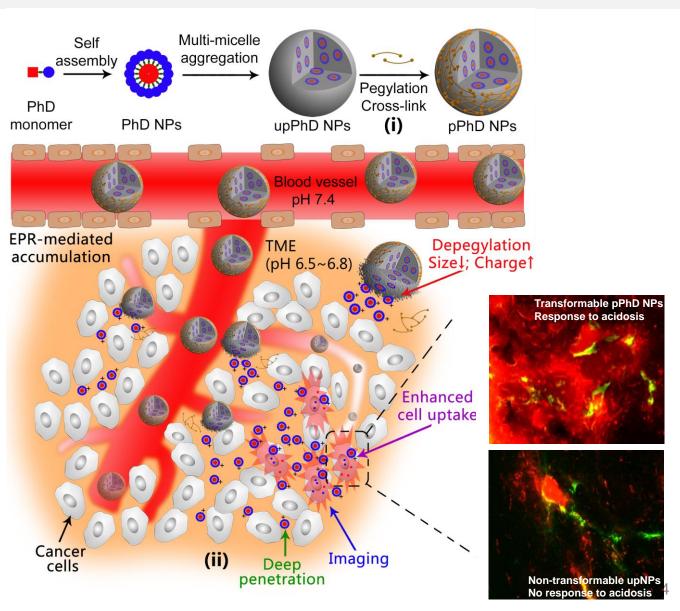


Theranostec Addresses 75% of Cases

Solution: Nanovehicles with Trimodal Therapeutic Activity

THERANOSTEC

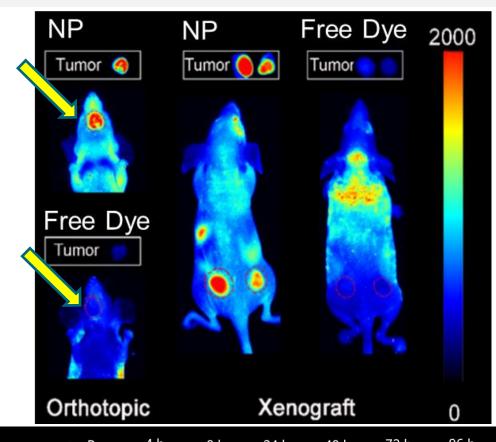
- "Trojan-Horse" nanovehicles made of cross-linked, selfassembling nanoparticles
 - High drug content
 - Excellent stability
- Unique trigger mechanism releases active compounds only in the presence of the tumor
 - Enhanced tumor accumulation & penetration
 - Reduced toxicity
 - Widened therapeutic window

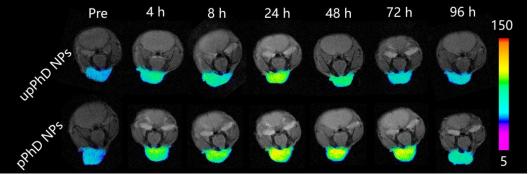


Improved Surgery Through Imaging-guidance



- TheraPhD can also be used as a tumor imaging agent
- Can be used to more easily delineate the tumor from healthy tissue
 - Increasing surgical precision
 - Reducing chance of tumor recurrence
- TheraPhD capable of dual imaging modalities
 - Near-infrared fluorescence imaging (NIRFI)
 - Magnetic resonance imaging (MRI)

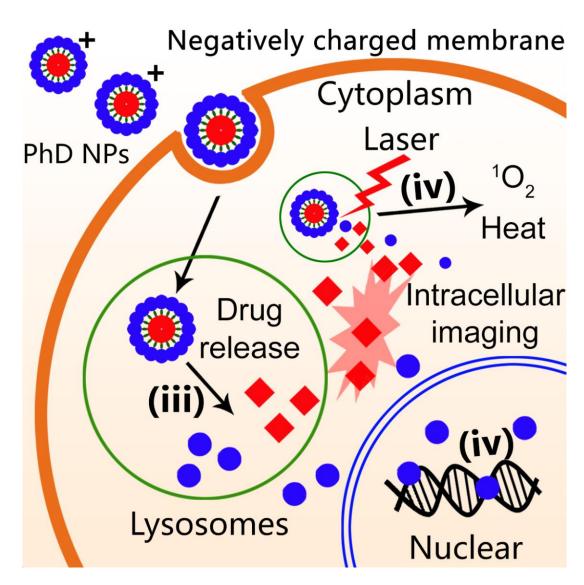




Treating Residual Tumor Through Phototherapy & Trimodal Therapeutic activity with TheraPhD

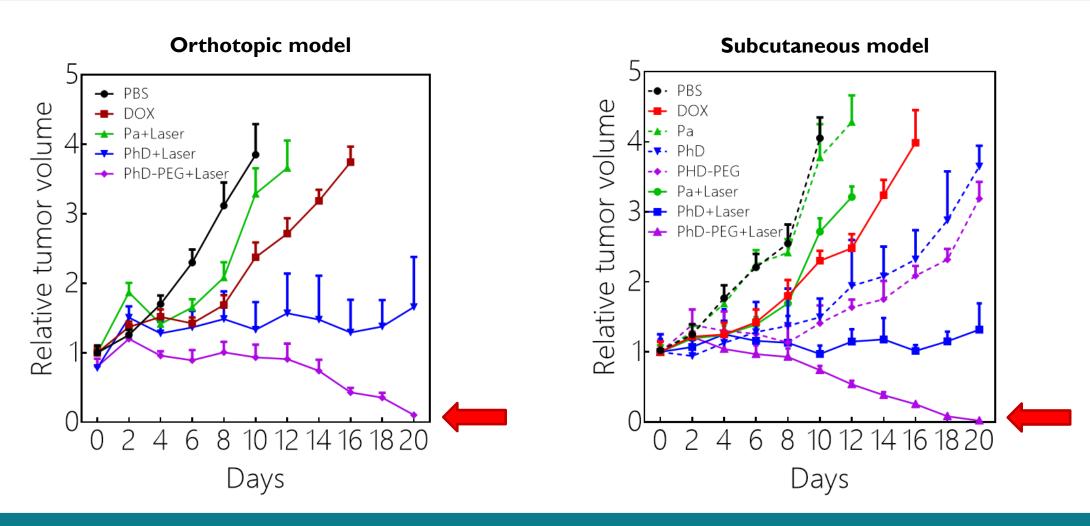


- Trimodal therapeutic activity combines chemo- and phototherapeutic activities
 - Chemotherapeutic,
 Photothermal, Photodynamic
- Targeted laser phototherapy amplifies the anti-tumor efficacy and prevents off-target activity
 - Phototherapy can be used to tune therapeutic effect to the desired level
 - Can be used post-surgery to clean up residual tumors



TheraPhD Has Extremely Positive In Vivo Activity





TheraPhD nanoparticles completely eliminated oral cancers in both models

Milestones & Funding



Development Stage	Preclinical POC	Pre-IND	Phase I					
Funding Required	\$300k	\$2M	\$18M (Series A)					
Milestones	 ✓ SBIR Phase I-funded ✓ Formulation Optimization ✓ Early In vivo evaluation ✓ PK/PD • Efficacy/ Toxicity evaluation • GMP production • CMC section development 							
Patents	 TheraPhD nanoparticle technology is currently under patent US Patent US2018/037895 							
Publications	Recent results published in Nature Communications (2018, 9, 3653)							
Funding	 Received SBIR Phase I grant to optimize activity/stability and evaluate the diagnostic and therapeutic activity in vivo (\$300k). A new NIH grant just awarded to the Dr. Li's lab at UC Davis to conduct studies in companion animals (3M). 							

Team and Advisors



Team



Dr. Yuanpei Li, PhD Founder & CEO

- Associate Professor of Biochemistry and Molecular Medicine at UC Davis
- Expert in nanotechnology and drug delivery



Dr. Cindy Lin, DVM, PhD Founder & COO

- Research Associate Professor at UC Davis
- Expert in both in vitro and in vivo studies



Advisors

Dr. Gregory Farwell, MD Chair of the Department of Head and Neck Surgery, UC Davis

- Expert in head and neck cancers
- 25 years experience as practicing surgeon



Dr. Rick Harkins, NIH CAP advisor

Prior Principal Scientist at Bayer Healthcare 35 years experience in the managing partnerships with U.S. academic research institutions and emerging life science firms



Dr. Aaron Lindstrom, PhD Principal Scientist

- Postdoctoral Scholar at UC Davis
- Expert in medicinal chemistry and drug design



Lloyd Kunimoto CEO of Amfora, Inc.

25 years experience in successfully leading biotechnology and biopharmaceutical companies

Theranostec Pipeline Drives Growth Potential



PROGRAM	INDICATION	DISCOVERY and OPTIMIZATION	IN VIVO TESTING	GMP, IND- ENABLING STUDIES	INI	D	CLINICAL TRIALS
TheraPhD Doxorubicin/Porphyrin	HNSCC, TNBC				1 1 1 1 1 1 1 1		
TheraNinja-V Vincristine	Pediatric Brian Cancer						
TheraTaxel Paclitaxel	Ovarian Cancer						
FUNDING		R01-SBIR	SBIR-Phase I	SBIR-Phase 2		Par	tnership/VC



Seeking \$20M in funding for IND filing and phase I clinical trials

- Completion of the GMP production of TheraPhD and IND-enabling Pharm/Tox Studies
- IND filing will follow completion of these results
- Phase I clinical trials in patients with solid tumors