

# (NASDAQ:DRTS) Investor Presentation

November 2025

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# Alpha Tau Overview

# AlphaPaRT

A novel approach using localized alpha particle radiotherapy designed to precisely destroy solid tumors while sparing surrounding healthy tissue



### Alpha DaRT Advantages

- Short-range radiation supporting safety + efficacy
- Broad potential applicability for local tumor control
- Signs of compelling immuno-stimulatory activity
- Potential to be utilized alone or synergistically with other cancer treatment modalities

### **Increasing Corporate Momentum**

- Multiple upcoming milestones in next 6 12 months
- Supportive dialogue with FDA and other regulators
- Massive potential TAM (10k's) in each indication
- Expanding global manufacturing network
- → 150 patents issued, > 200 applications pending
- **Mell financed to execute on current goals**

# **Anticipated Milestones**

Regulatory

Clinical

Geography	Target Indication	Q4 2025	H12026	H2 2026
	Recurrent Cutaneous SCC		Complete multi- center pivotal recruitment	Data Readout + Potential FDA submission
United States	Pancreatic Cancer		Complete Recruitment in Pilot Study	Initial Readout from Pilot Study
	Recurrent GBM	First Patient in Pilot Study		
Japan	Head & Neck Cancer	PMDA Response		

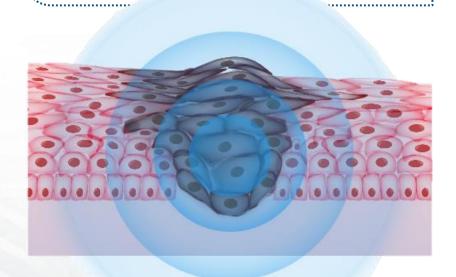
**AlphaTAU** 

# Alpha Radiation is Focal - Short Range Limits Clinical Use

Whereas beta and gamma radiation can penetrate tissue with sufficient range to facilitate tumor coverage (while risking damage to healthy tissue), alpha radiation has short range in tissue ( $< 100 \, \mu m$ ), which limits its clinical usefulness in local delivery

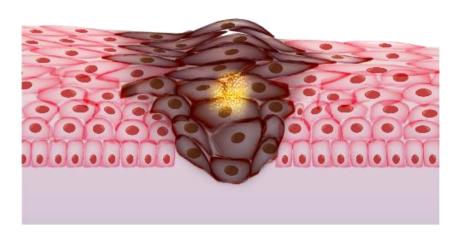
### **Beta/Gamma Radiation**

Long therapeutic range with risk to surrounding organs



### **Alpha Radiation**

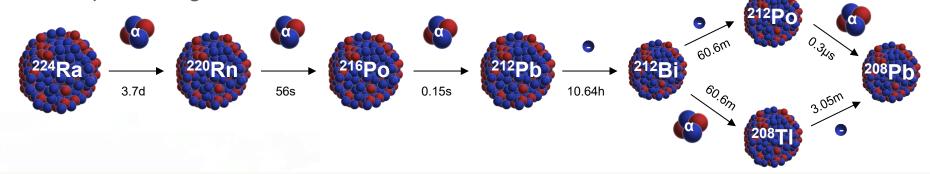
Short range in tissue limits damage to surrounding organs but also limits coverage



# Alpha DaRT Technology is Designed to Overcome These Limitations

### <sup>224</sup>Ra Decay Chain

- Alpha DaRT leverages the innate decay chain of Radium-224
- The decay chain of Radium-224 includes four alpha particles
- Radium-224 has a half-life of ~3.7 days, while the remaining decay chain has a total half-life of approximately 12 hours, before eventually stabilizing in inert form



### Alpha DaRT

- The Alpha DaRT utilizes stainless steel or titanium sources that are impregnated with Radium-224
- When the Alpha DaRT source is injected into the tumor, the radium remains attached to the source while its daughter atoms detach, emitting cytotoxic alpha particle payloads as they move deeper into the tumor until eventually stabilizing

Alpha DaRT is designed to overcome the range limitations of alpha particles through precise release of alpha emitters into the tumor, generating a potent and tight distribution of alpha radiation

# Alpha DaRT - Diffusing Alpha-emitters Radiation Therapy

https://www.youtube.com/watch?v=nwfzJHm0fTQ

# **Therapeutic Focus**

We are focused on delivering solutions to three markets that we believe would be best served by the unique characteristics of the Alpha DaRT

### Localized & Unresectable

- Localized tumors that are not surgical candidates and tumors that recur after surgery and are resistant to other therapies, specifically radiotherapy
- Alpha DaRT to be evaluated as a later line therapy
- Tumor types we are targeting include SCC, H&N SCC and prostate



### Metastatic

- Alpha DaRT being evaluated for its potential to induce an immune response in metastatic tumors
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### **High Unmet Need**

- Solid tumors that have limited treatment options with limited standard of care offering
- Alpha DaRT could potentially target broad patient populations
- Tumor types we are targeting include GBM and pancreatic cancer



# **Initial Foray into Superficial Tumors**

Alpha DaRT first tested in superficial tumors – tumors of the skin or head & neck, due to:

- Ease of access
- **⊘** Straightforward control
- Ongoing monitoring
- Strong initial preclinical data in Squamous Cell Carcinoma (SCC)

### Treatment of hundreds of tumors to date:

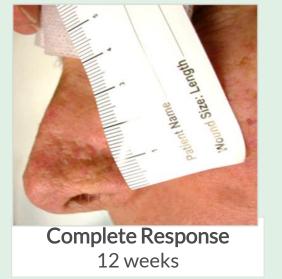
- Indicated a mild safety profile
- Generated marketing authorization in Israel to treat SCC of the skin or oral cavity
- Allowed us to submit to PMDA in Japan for marketing authorization to treat recurrent head & neck cancer

Pivotal trial ("ReSTART") underway in the U.S. for recurrent cutaneous SCC

# U.S. Skin Cancer Pilot Study Leading to Pivotal Study

U.S. Pilot Feasibility Study			
Locations	5 centers – led by Memorial Sloan Kettering Cancer Center		
# of Patients Treated	10		
Adverse Events	22 reported AE's, most were mild or moderate No treatment-related serious AEs		
Response Rate	100% Complete Response Rate		

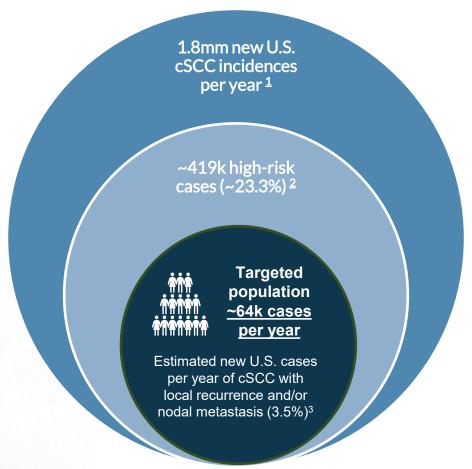




Multicenter Pivotal Recurrent SCC Study			
Locations Multiple centers, including UCLA, Emory University, Mayo Clinic, etc.			
# of Patients	86		
Primary Objectives	Objective Response Rate, Durability of Response @ 6 months, adverse events assessment		
Targeted Completion of Recruitment	Q1 2026		

Feasibility and Safety of Diffusing Alpha-Emitter Radiation Therapy

# Potential cSCC Patient Breakdown - Estimated U.S. Incidence



<sup>&</sup>lt;sup>1</sup> https://www.skincancer.org/blog/our-new-approach-to-a-challenging-skin-cancer-statistic/

<sup>&</sup>lt;sup>2</sup> Evaluation of American Joint Committee on Cancer, International Union Against Cancer, and Brigham and Women's Hospital Tumor Staging for Cutaneous Squamous Cell Carcinoma

Pritesh S. Karia, Anokhi Jambusaria-Pahlajani, David P. Harrington, George F. Murphy, Abrar A. Qureshi, and Chrysalyne D. Schmults. Journal of Clinical Oncology 2014 32:4, 327-334

<sup>&</sup>lt;sup>3</sup> Factors Predictive of Recurrence and Death From Cutaneous Squamous Cell Carcinoma: A 10-Year, Single-Institution Cohort Study

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### **High Unmet Need**

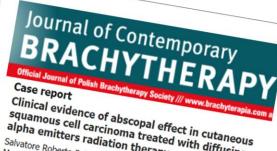
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# Case Study: Potential Systemic Immune Effect Observed in One cSCC Patient Where a Second, Untreated Lesion Manifested CR



Complete Response + Potential Systemic Immune Effect

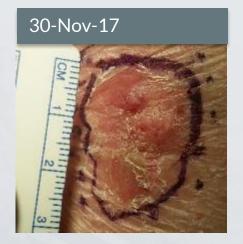


squamous cell carcinoma treated with diffusing alpha emitters radiation therapy: a case report

Salvatore Roberto Bellia, Giacomo Feliciani, Massimo Del Duca, Manuela Monti, Valentina Turri, Anna Sarnelli, Antonino Romeo , Itzhak Kelson, Yona Keisari, Aron Popovtzer, Toni Ibrahim,

### **Treated Tumor**

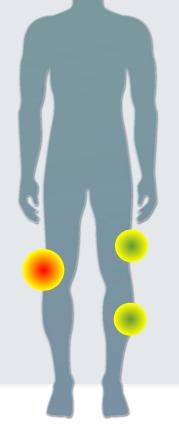
### Before



### After







### **Untreated Tumors**

### Before



### After



# Outline of Checkpoint Inhibitor Combination Trial – CTP-HNCPI-00

### Key Eligibility Criteria



Recurrent unresectable or metastatic head and neck squamous cell carcinoma (like KEYNOTE-048)

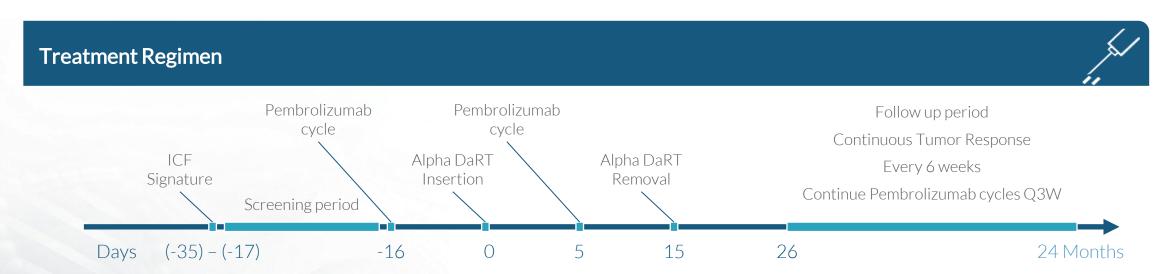
No previous treatment for metastatic disease

### **Benchmark Comparator**



KEYNOTE-048: Benchmark comparator data for 1L Pembrolizumab in patients with recurrent or metastatic HNSCC<sup>1</sup>

Population	Benchmark Regimen	Systemic ORR	Systemic CR %
PD-L1 CPS ≥ 20	Pembrolizumab Alone	23%	8%
PD-L1 CPS ≥ 1	Pembrolizumab Alone	19%	5%
Total population	Pembrolizumab Alone	17%	5%



<sup>1</sup>Benchmark data provided for illustrative purposes only. Not a head-to-head trial Source: Burtness, B. et al (2019). Pembrolizumab alone or with chemotherapy versus cetuximab with chemotherapy for recurrent or metastatic squamous cell carcinoma of the head and neck (KEYNOTE-048): a randomised, open-label, phase 3 study. The Lancet. doi:10.1016/s0140-6736(19)32591-7

AlphaTAU

# Early Interim Data Show Strong Systemic Responses

- As of January 9, 2025, eight patients were treated with Alpha DaRT and pembrolizumab in the study
- Baseline characteristics:
  - 3 female / 5 male
  - Mean age of 73 years (range 61-96)
  - 6mHNSCC/2laHNSCC
- Patients received an average of 4 cycles of pembrolizumab (range 2-9)
- Systemic responses observed:
  - Three complete responses
  - Three partial responses
  - Two patients died prior to evaluation
- Only two Alpha DaRT-related adverse events, both were Grade 1 (mild)

37.5%
Systemic Complete Responses

75%
Systemic Objective
Response Rate
(CR + PR)

No Related SAEs

HNCPI-00-01-003

Pembrolizumab Combination Case Study

# Case Background – HNCPI-00-01-003

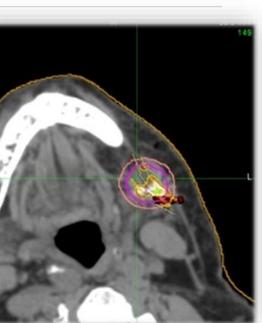
Age	96		
Sex	Female		
Tumor Type	SCC		
Date of First Diagnosis	Jul-2022		
Location	Alveolar ridge & lip plus dermal involvement		
Prior Treatments	None		
Medical Background	• Cardio		

Dementia

ECOG3

Stage IV T2N1M1

Cancer Stage





# Alpha DaRT Treatment



Alpha DaRT Insertion Sept-2022



After Alpha DaRT Removal Oct-2022



Follow-Up

Jan-2023

# **Clinical Follow-Up**



**Pre-Treatment** 

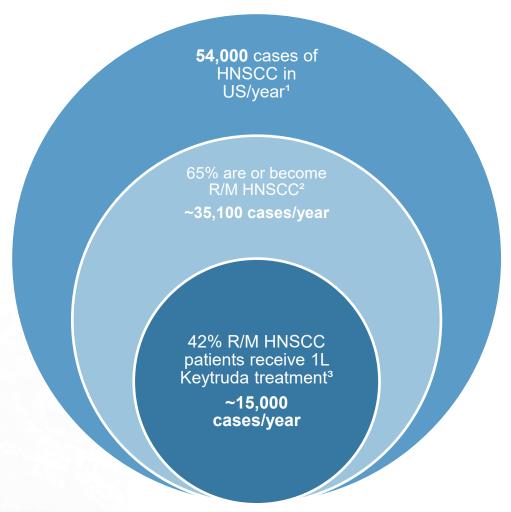


Nine Weeks Post Treatment

### **Patient Status**

- Patient stopped Pembrolizumab after 12 months
- Patient still alive with no evidence of disease at October 2024 followup

# **HNSCC Patient Breakdown**



<sup>&</sup>lt;sup>1</sup>Epidemiology, Risk Factors, and Prevention of Head and Neck Squamous Cell Carcinoma Adam Barsouk, John Sukumar Aluru, Prashanth Rawla, Kalyan Saginala, Alexander Barsouk. Med. Sci. 2023, 11(2), 42; https://doi.org/10.3390/medsci11020042

<sup>&</sup>lt;sup>2</sup>Recent Advances and Future Directions in Clinical Management of Head and Neck Squamous Cell Carcinoma Jameel Muzaffar, Shahla Bari, Kedar Kirtane, Christine H. Chung Cancers 2021, 13(2), 338; <a href="https://doi.org/10.3390/cancers13020338">https://doi.org/10.3390/cancers13020338</a>
<sup>3</sup>Real-world treatment patterns and outcomes among individuals receiving first-line pembrolizumab therapy for recurrent/metastatic head and neck squamous cell carcinoma Christopher M Black, Glenn J Hanna, Liya Wang, Karthik Ramakrishnan, Daisuke Goto, Vladimir Turzhitsky, Gleicy M Hair Front Oncol. 2023 May 22;13:1160144. <a href="https://doi.org/10.3389/fonc.2023.1160144">https://doi.org/10.3389/fonc.2023.1160144</a>

Alpha

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# Focus on Internal Organ Treatments

We continue to make progress across internal organ programs, with trials underway in multiple targeted indications and others in various stages of planning and start-up

### **Internal Organs in Focus**

- Pancreas clinical trial underway
- Liver clinical trial underway
- Lung clinical trial underway
- Prostate clinical trial underway
- Brain GBM + Brain Mets
- Breast
- Rectum













# Interim Pancreatic Cancer Results - Overview of Trial Design

Three trials treating pancreatic cancer patients in parallel:

- CTP-PANC-101 monotherapy treatment at 2 sites in Montreal, Canada up to 37 patients total
- CTP-PANC-02 monotherapy treatment at 1 site in Jerusalem, Israel up to 15 patients total
- CTP-ALL-00 flexible basket trial at 1 site in Jerusalem, Israel no specified limit on number of patients

Following initial results, there are some situations where chemotherapy has been used in the first two trials

- CTP-PANC-101 allows chemotherapy 30 days after Alpha DaRT treatment
- CTP-PANC-02 was modified to allow concomitant chemotherapy

Therefore, after initially embarking on monotherapy exploration, a small number of patients from all three trials have received chemotherapy treatment alongside or following Alpha DaRT treatment

Due to the exploratory nature of the trials, they do not focus on a specific patient sub-population but rather a broad mix of patients with non-resectable pancreatic cancer

# High Disease Control Rate Observed

Among the 41 patients treated, 33 had a measured objective response, with 5 patients awaiting response evaluation and 3 who discontinued prior to evaluation. Results are presented below using Best Overall Response (BOR) for those with a measured response.

Including first two patients (heavily underdosed / feasibility only)

18%
Objective Response Rate (CR + PR)

91%
Disease Control Rate (CR + PR + SD)

Excluding first two patients (heavily underdosed / feasibility only)

19%
Objective Response Rate (CR + PR)

97%
Disease Control Rate
(CR + PR + SD)

Note: Results as of January 8, 2025

# Highlights of Overall Survival (OS) Data

### **Key Caveats:**

- The data are still relatively immature, but ongoing
- Trial designs were **focused on feasibility and safety**, without the frequent monitoring visits common in studies focused on precise measurement of survival
- Five patients treated since Nov 25, 2024, and three patients who exited the study very shortly after treatment, in all cases with insufficient time to reach objective response measurement, were excluded from OS analysis for lack of data maturity
  - Therefore, a total of n = 33 patients are evaluated for OS using Kaplan-Meier analysis

	OS Since Diagnosis /	
	Initiation of Last	OS Since Alpha DaRT
Population	Chemotherapy (mo)	Treatment (mo)
		_
Overall Population (n=33)	18.6	10.9

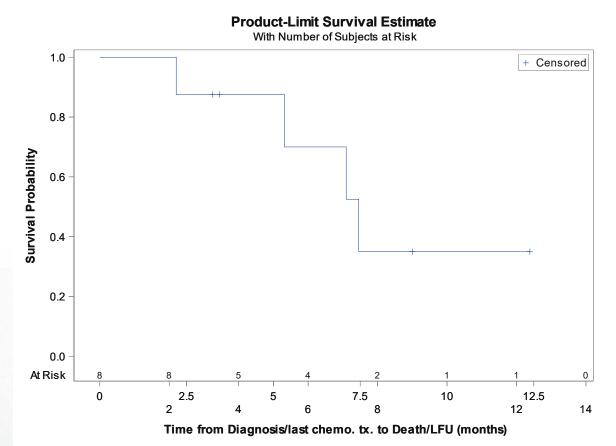
### Of n=33 patients analyzed, 13 have died The remaining 20 (and the five newer patients) remain alive

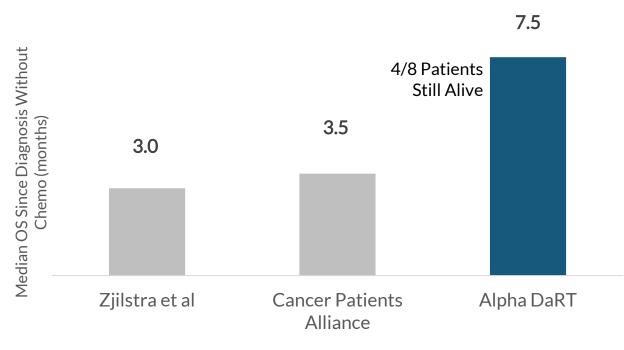
In light of the **heterogeneity of the population**, we conducted ad-hoc analyses **of key sub-groups** to offer context vs. expected OS for each group

Note: Results as of January 8, 2025

# Analysis of Overall Survival in Key Sub-Populations (1/3)

### Newly Diagnosed / Not Eligible for Chemotherapy (n=8)





Note: Median follow-up in Alpha DaRT group of 6.3 months

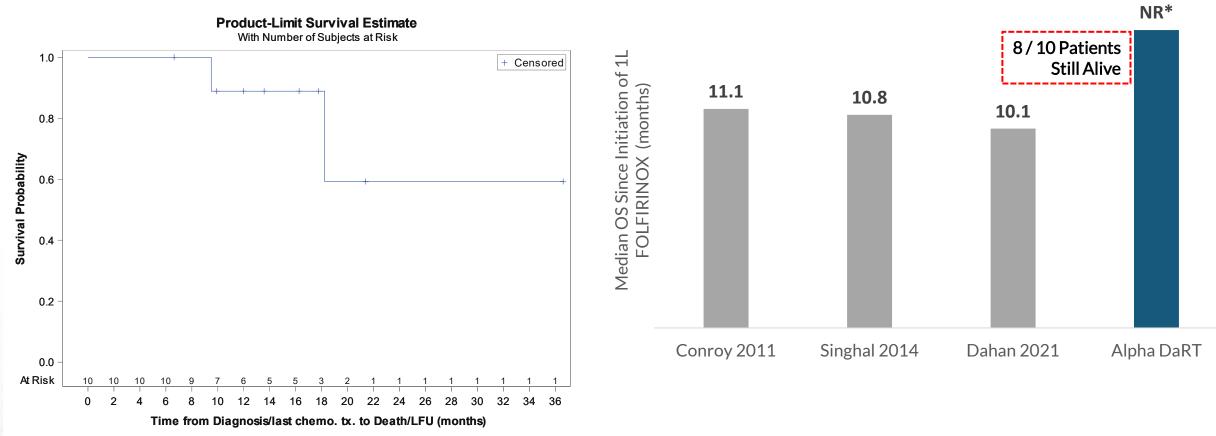
Results as of January 8, 2025

For Illustrative Purposes Only - no head-to-head clinical study has been conducted comparing Alpha DaRT to other products or candidates. Differences exist between trial designs, subject characteristics and other factors, and caution should be exercised when comparing data across unrelated studies

Sources:

Zijlstra, M. et al (2018). Patient characteristics and treatment considerations in pancreatic cancer: a population based study in the Netherlands. https://doi.org/10.1080/0284186X.2018.1470330 https://pancreatica.org/pancreatic-cancer/pancreatic-cancer-prognosis/

# Analysis of Overall Survival in Key Sub-Populations (2/3) Metastatic (Stage IV) Patients After 1L FOLFIRINOX (n=10)



<sup>\*</sup> Median Kaplan-Meier estimate was not reached (NR): median follow-up time was 15.1 months

For Illustrative Purposes Only - no head-to-head clinical study has been conducted comparing Alpha DaRT to other products or candidates. Differences exist between trial designs, subject characteristics and other factors, and caution should be exercised when comparing data across unrelated studies

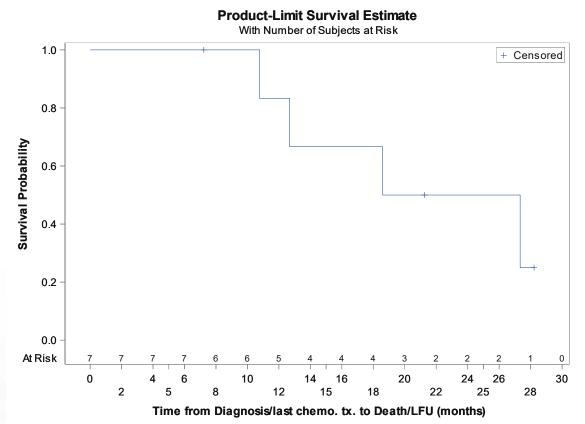
Note: Results as of January 8, 2025

Sources:

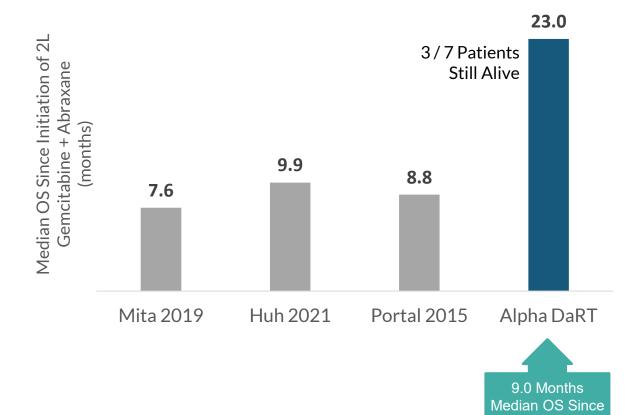
Thierry Conroy et al., FOLFIRINOX versus Gemcitabine for Metastatic Pancreatic Cancer. New England Journal of Medicine (2011). DOI: 10.1056/NEJMoa1011923 Singhal MK, et al. A phase III trial comparing FOLFIRINOX versus gemcitabine for metastatic pancreatic cancer. Ann Oncol. 2014;25(suppl 4):iv210–53. Laetitia Dahan et al., Randomized Phase II Trial Evaluating Two Sequential Treatments in First Line of Metastatic Pancreatic Cancer:

# Analysis of Overall Survival in Key Sub-Populations (3/3)

### Progressed After 2L Gemcitabine-Abraxane (n=7)



2015 Sep 29;113(7):989-95. doi: 10.1038/bjc.2015.328. Epub 2015 Sep 15. PMID: 26372701; PMCID: PMC4651133.



Note: Median follow-up in Alpha DaRT group of 18.9 months

For Illustrative Purposes Only - no head-to-head clinical study has been conducted comparing Alpha DaRT to other products or candidates. Differences exist between trial designs, subject characteristics and other factors, and caution should be exercised when comparing data across unrelated studies

Note: Results as of January 8, 2025

Source:

Mita N. Iwashita T. Uemura S. Yoshida K. Iwasa Y. Ando N. Iwata K. Okuno M. Mukai T. Shimizu M. Second-Line Gemcitabine Plus Nab-Paclitaxel for Patients with Unresectable Advanced Pancreatic Cancer after First-Line FOLFIRINOX Failure. J Clin Med. 2019 May 29;8(6):761. doi: 10.3390/jcm8060761. PMID: 31146420; PMCID: PMC6616879 Huh G, Lee HS, Choi JH, Lee SH, Paik WH, Ryu JK, Kim YT, Bang S, Lee ES. Gemcitabine plus Nab-paclitaxel as a second-line treatment following FOLFIRINOX failure in advanced pancreatic cancer: a multicenter, single-arm, open-label, phase 2 trial. Ther Adv Med Oncol. 2021 Nov 10;13:17588359211056179. doi: 10.1177/17588359211056179. PMID: 34790261; PMCID: PMC8591648. Portal A et al. Nab-paclitaxel plus gemcitabine for metastatic pancreatic adenocarcinoma after Folfirinox failure: an AGEO prospective multicentre cohort. Br J Cancer. AlpheTAU

Alpha DaRT

# Pancreatic Cancer Clinical Trial: FDA Approval of IDE for U.S. Pilot

N=15



Newly Diagnosed
Locally Advanced
Pancreatic Cancer

N=15



Newly Diagnosed

Metastatic Pancreatic

Cancer

**AlphaDaRT** 

Insertion

(During Cycles 1-4)

8-12 cycles of **mFOLFIRINOX** 

**Primary Endpoint:** 

Incidence of Treatment-Emergent Adverse Events

2

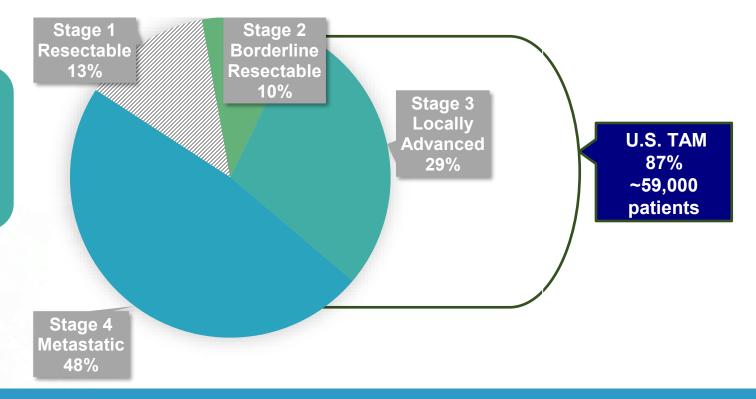
**Secondary Endpoints:** 

Overall Survival
Progression-Free Survival
Pain Improvement
Surgical Resectability (LA
cohort only)

# Pancreatic Cancer: Massive and Growing Unmet Need

There are over half a million new cases of pancreatic cancer per year. Approx. 66k of them are in the U.S.

Incidence rate of pancreatic cancer is trending upward, especially in younger patients



At diagnosis, 87% of pancreatic cancer cases are not eligible for surgical resection and/or have metastasized

Note: Excludes cancers of stage "unknown" or "N/A" - data from 1400 Hospitals

Source: https://www.facs.org/media/ztllhkfu/cancer-cases-reported-to-the-ncdb-by-tumor-type-and-ajcc-stage.pdf

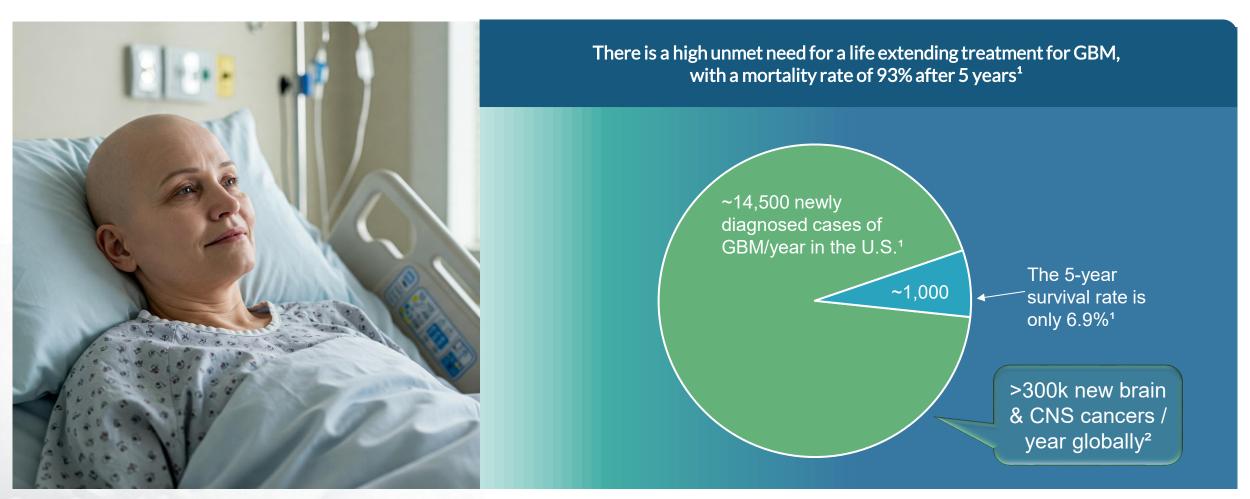
https://gco.iarc.who.int/media/globocan/factsheets/cancers/13-pancreas-fact-sheet.pdf

https://www.cancer.org/cancer/types/pancreatic-cancer/about/key-statistics.html

https://www.thelancet.com/journals/langas/article/PIIS2468-1253%2823%2900039-0/fulltext

## The Next Frontier: Glioblastoma Multiforme (GBM) / Brain Cancers

GBM is one of the most complex, deadly, and treatment-resistant cancers, with an average length of survival estimated at only 8 months<sup>1</sup>. Alpha Tau has IDE approval to initiate a U.S. pilot study in GBM.



¹https://braintumor.org/events/glioblastoma-awareness-day/about-glioblastoma/ ²https://gco.iarc.who.int/media/globocan/factsheets/cancers/31-brain-central-nervous-system-fact-sheet.pdf

# Radial Applicator & Pre-Clinical Study in Swine Brain

# Alpha Radial Applicator for the Delivery of Alpha DaRT into the Brain

Designed to deliver sources in precise spacing while minimizing damage to the brain



A stereotactic biopsy needle is inserted into the target area of the brain. The alpha radial applicator is affixed to the biopsy needle hub



The physician pushes the flexible applicator tube into the tumor, and once in place, pushes the stylet forward and retracts the tube



The needle is then rotated to the next position, to deliver a layer of sources without inserting the needle repeatedly



RESEARCH

Stereotactic implantation of diffusing alpha-emitters radiation therapy sources in the swine brain: a potential new focal therapy for brain tumors

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### Pre-Clinical (Swine) Study Results

- Alpha-DaRT sources were reproducibly and efficiently delivered to the brain cortex and subcortex
- No unexpected abnormalities in blood / CSF
- No evidence of major bleeding or infection
- Minimal spacial and temporal movements of sources

Conclusion: Alpha-DaRT sources can be safely delivered into a large animal brain using image-guided stereotactic implantation

# Therapeutic Focus

We are focused on delivering solutions to three markets that we believe would be best served by the unique characteristics of the Alpha DaRT

### Localized & Unresectable

- Localized tumors that are not surgical candidates and tumors that recur after surgery and are resistant to other therapies, specifically radiotherapy
- Alpha DaRT to be evaluated as a later line therapy
- Tumor types we are targeting include SCC, H&N SCC and prostate

### Metastatic

- Alpha DaRT being evaluated for its potential to induce an immune response in metastatic tumors
- Alpha DaRT being evaluated in combination with checkpoint inhibitors as an adjuvant therapy
- Tumor types we are targeting include liver, breast and H&N (which includes lip, oral cavity, salivary glands, oropharynx & pharynx) cancers

### **High Unmet Need**

- Solid tumors that have limited treatment options with limited standard of care offering
- Alpha DaRT could potentially target broad patient populations
- Tumor types we are targeting include GBM and pancreatic cancer



# **Anticipated Milestones**

Regulatory

Clinical

Geography	Target Indication	Q4 2025	H12026	H2 2026
	Recurrent Cutaneous SCC		Complete multi- center pivotal recruitment	Data Readout + Potential FDA submission
United States	Pancreatic Cancer		Complete Recruitment in Pilot Study	Initial Readout from Pilot Study
	Recurrent GBM	First Patient in Pilot Study		
Japan	Head & Neck Cancer	PMDA Response		

**AlpheTAU** 

# **Global Manufacturing Facilities**

For efficient commercial operations, we look to establish manufacturing operations in multiple regions of the world, to enable relatively short shipping times to our core markets. We are currently building our first commercial-scale facility in Hudson, NH



Hudson, New Hampshire (First Phase License Received – ~400,000 local sources per year)



Lawrence, Massachusetts (Operational – Producing Generators)



Jerusalem (Operational ~200,000 local sources per year)



Jerusalem (In Planning)



Togane, Japan (In Planning)



### **Financial Position**



Public Since Mar-2022 (NASDAQ:DRTS)



\$75.9mm in Cash & Deposits at Q3 2025



Well Financed for Execution



# AlphaTAU Saving Lives Globally

