

# (NASDAQ:DRTS) Company Overview

July 2022

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### Alpha Tau – Key Investment Highlights





Broad potential and preclinical evidence supporting evaluation across various solid tumors (skin, pancreas, breast, GBM, etc.) with 18 peer-reviewed pre-clinical papers



Compelling potential immuno-stimulatory effect and synergetic combination with other therapies

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Exhibited 100% ORR and ~78% CR in first-in-human clinical trial in 28 SCC tumors. Over 100 superficial tumors treated to date, with a similar profile observed. 100% CR seen at 12 weeks in 1<sup>st</sup> US study

Favorable safety profile observed, no systemic toxicities



Robust clinical-trial strategy with leading global centers, with U.S. pivotal study forthcoming in recurrent cutaneous SCC. Two FDA Breakthrough Device Designations (skin & GBM)



Solid logistics based on purpose-built manufacturing facilities, built or in planning, in the US, Israel and Asia, with a highly scalable and optimized proprietary production process



Strong intellectual property (method and device) with over 160 issued and pending patents worldwide



**AlpheTAU** 

Experienced management team, including Alpha DaRT's co-inventors, with expertise in oncology development, manufacturing scale up and commercialization

## **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 include SCC, H&N
   SCC and prostate



#### High Unmet Need

- Solid tumors that have **limited treatment options** with limited SOC offering
- Alpha DaRT could potentially target **broad patient populations**
- Tumor types include **GBM and** pancreatic cancer



#### Metastatic

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



### **Development Pipeline**

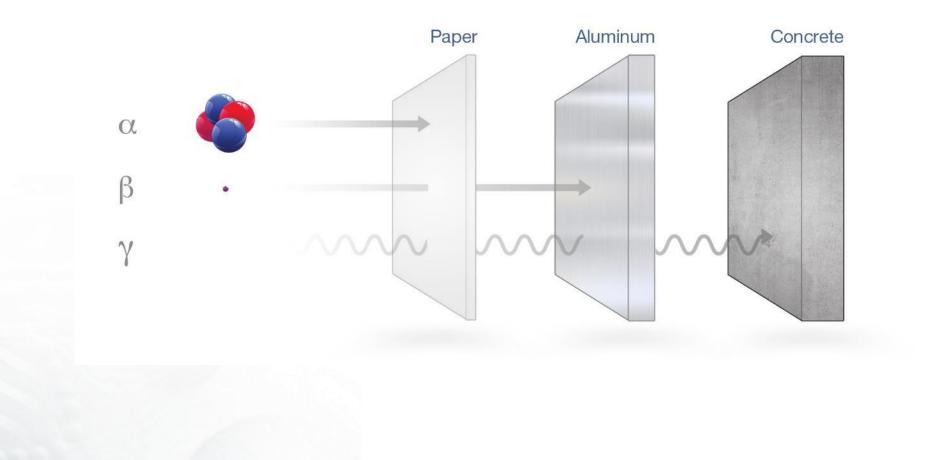
Our clinical trial strategy involves progressing our lead program (superficial tumors), particularly in the US, and conducting feasibility studies in other tumors to evaluate the Alpha DaRT in tumors of high unmet need or metastatic disease
 FDA Breakthrough Device Designation received for certain uses in skin cancer and GBM

| Geography         | Indication                              | Pre-Clinical<br>Research | Feasibility<br>Trial | Pivotal Trial | Marketing<br>Authorization | Anticipated Milestones  |
|-------------------|---|--------------------------|----------------------|---------------|----------------------------|---|
|                   | Skin Cancers                            | U.S.                     |                      |               |                            | <ul> <li>First patient into US pivotal trial targeted<br/>for 2H 2022</li> </ul>          |
| North America     | Pancreatic Cancer                       | Canada                   |                      |               |                            | • First patient in feasibility trial 2H 2022  |
|                   | Liver Cancer                            | Canada                   |                      |               |                            | Trial in planning   |
|                   | Skin & Oral SCC                         |                          |                      |               |                            |   |
|                   | All Skin & Oral Cancers                 |                          |                      |               |                            | Trial completion and submission   |
| Israel            | la/mHNSCC (combo<br>with pembrolizumab) |                          |                      |               |                            | • Feasibility combination trial with Keytruda initiated 4Q 2021; awaiting interim results |
|                   | Pancreatic Cancer                       |                          |                      |               |                            | Initiate feasibility trial 4Q 2022  |
|                   | Breast Cancer                           |                          |                      |               |                            | Trial in planning   |
|                   | Prostate Cancer                         |                          |                      |               |                            | • Trial initiated 2Q 2022 – data ~2Q 2023   |
| _                 | Skin Cancers                            |                          |                      |               |                            | Trials underway   |
| Europe            | Pancreatic Cancer                       |                          |                      |               |                            | Trial in planning   |
|                   | Head & Neck SCC                         |                          |                      |               |                            | Potential PMDA submission in 3Q 2022  |
| Japan             | Breast Cancer                           |                          |                      |               |                            | Trial underway  |
| Additional Tumors | Hepatic Cell<br>Carcinoma , GBM, lung   |                          |                      |               |                            | Development / pre-clinical trials underway  AlpheTAU 5                                    |

### **Types of Radioactive Decay**

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Due to the mass of the alpha particle, in comparison to beta particle, alpha has a low penetration power. This means that the outside layer of the human skin, for example, can block these particles.



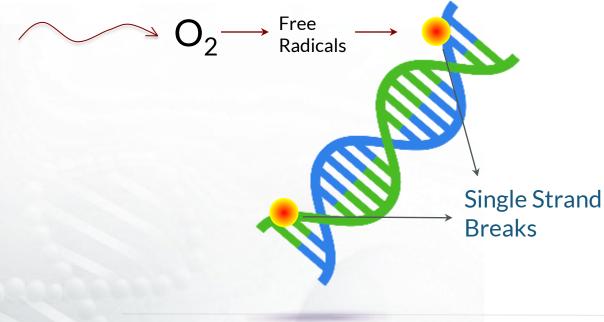
### Potent Alpha Radiation: Extensively Damages the DNA

Local radiation therapy with gamma or beta radiation is a mainstay of cancer treatment, but requires high local dose to be effective, as it primarily relies on single-strand breaks in a process relying on oxygen. Alpha radiation can be significantly more efficient given its ability to destroy both strands of the DNA directly, requiring lower levels of radiation

#### **Conventional Gamma/Beta Radiation**

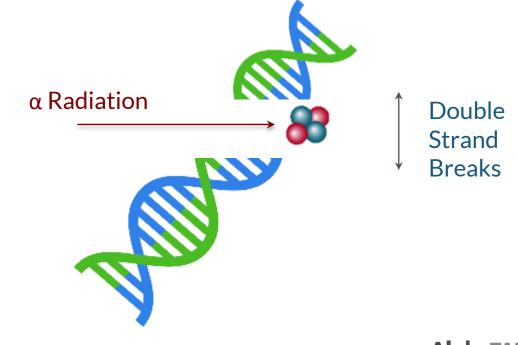
- Indirectly damaging the DNA
- Dependent on oxygen presence
- Repairable single strand breaks

#### $\gamma/\beta$ Radiation



#### **Alpha Radiation**

- Directly damaging the DNA
- Independent of oxygen presence
- Irreparable double strand breaks

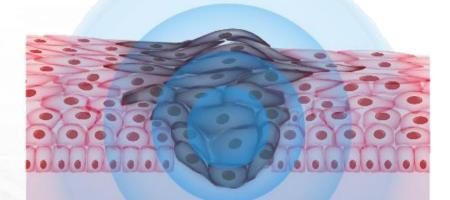


### Alpha Radiation is Focal - Short Range Limits Clinical Use

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 µm), which limits its clinical usefulness in local delivery

#### **Beta/Gamma Radiation**

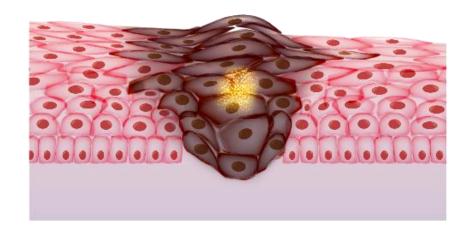
Long therapeutic range with risk to surrounding organs



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#### **Alpha Radiation**

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



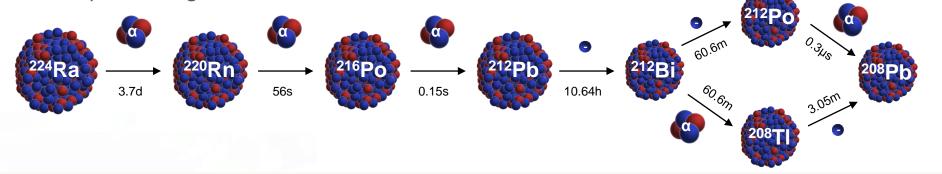
### Mechanism of Action of the Alpha DaRT Technology

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



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 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

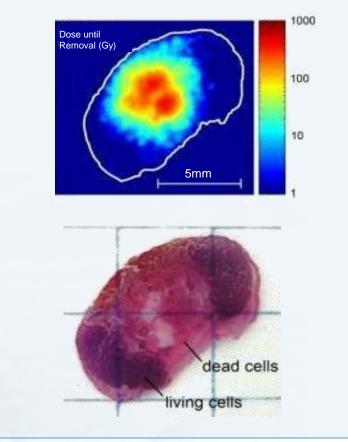
Alpha DaRT is designed to overcome the range limitations of alpha particles through precise release of alpha emitters into the tumor, generating a potent and tight distribution of alpha radiation

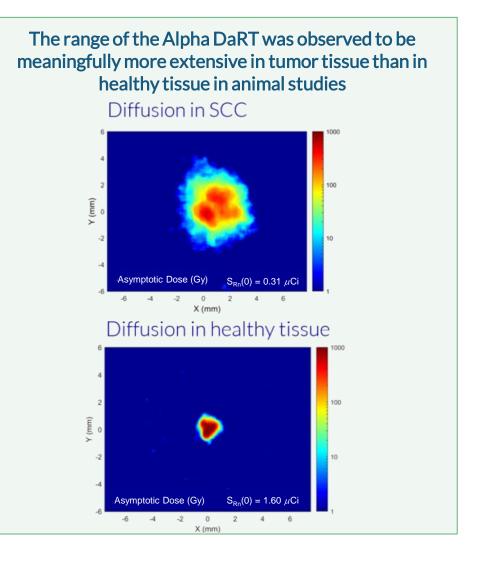
### Alpha DaRT - Diffusing Alpha-emitters Radiation Therapy

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

### Alpha DaRT Has a Unique Potential to Preserve Healthy Tissues

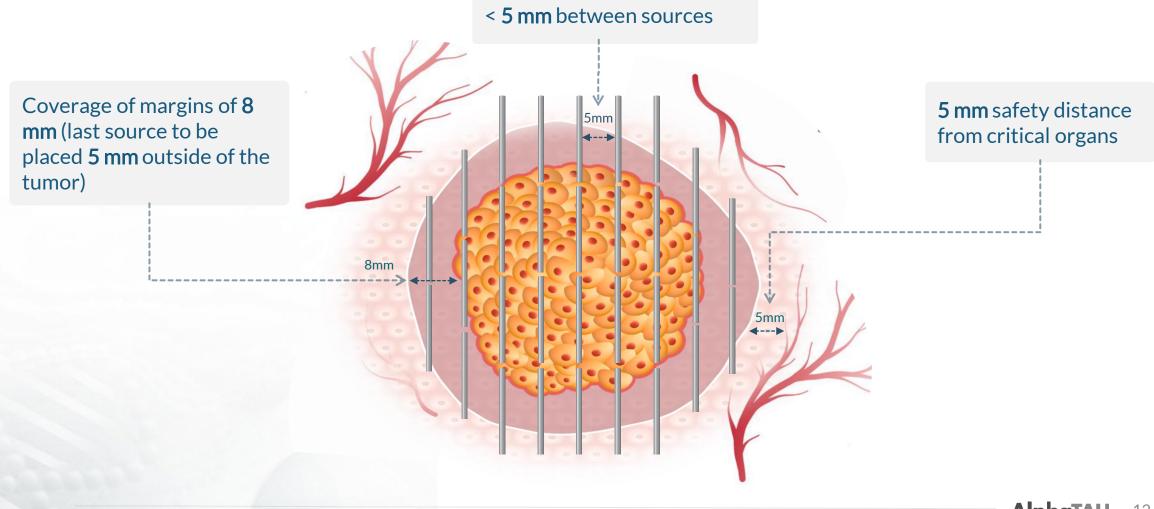
Alpha DaRT is unique in its potential to deliver a high dose of radiation in a very conformal form, with sharp dose drop-off outside of a 5mm range





### Alpha DaRT Source Placement

Through a series of Alpha DaRT injections to the tumor, spread a few millimeters apart, a clinician can potentially deliver alpha radiation to the full geometry of the tumor while taking care to avoid sensitive healthy tissue around the tumor



#### **Intra-tumoral Delivery Methods**

We Have a Total of Seven Applicators Which Have Been Developed for a Range of Potential Uses to Accommodate for:

Treatment Delivery Method Duration of Implantation

**Tumor Location** 

Our Applicators Allow Us Flexibility to Deliver Alpha DaRTs Into Both Superficial and Internal Tumors

#### **Temporary Implants (Superficial Tumors)**

Applicators are supplied preloaded, sealed and designed for immediate use in the procedure room

Sources are hollow and strung onto a surgical suture, allowing the clinician to insert the sources into the tumor and leave the suture in place

Alpha DaRT Needle Applicator

Example Indication: Superficial Tumors. sources are affixed to a biocompatible suture and loaded inside the needle







Example Indication: Pancreatic Tumors. Device is designed to be fitted to existing needles such as standard Fine Needle Aspirator (FNA) to ultimately deliver sources into the tumor

#### Permanent Implants (Internal Tumors)

Applicators are supplied preloaded or unloaded, and are designed to allow clinicians flexibility to load the sources in the course of treatment and to select how many sources to deliver



Procedure: FNA in Conjunction with Endoscopic Ultrasound



#### Response Observed in All Tested Solid Tumors in Preclinical Studies

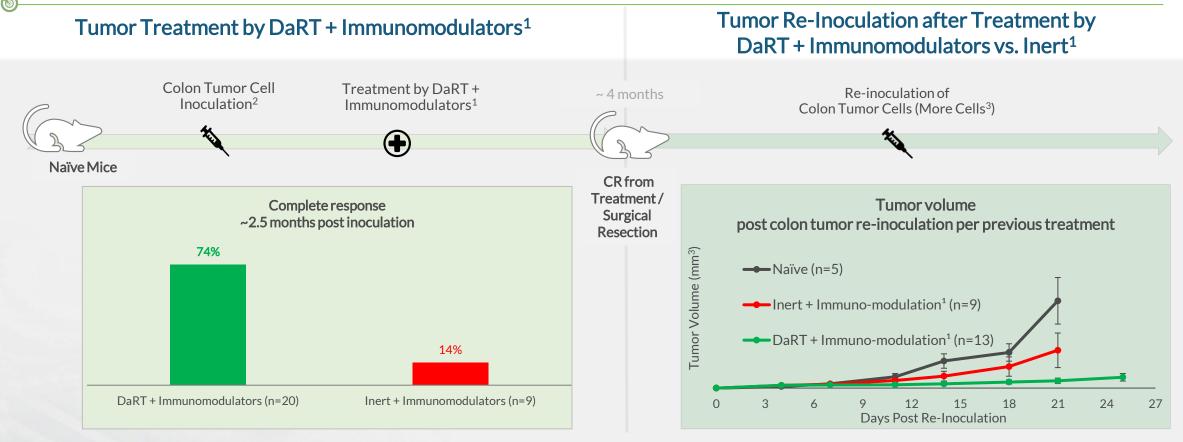
**18** Published Preclinical Studies in Peer-Reviewed Journals

Across a variety of tumor types, we have not observed resistance to the radiation delivered by the Alpha DaRT

| Squamous Cell Carcinoma         | Colon Carcinoma         |
|---------------------------------|-------------------------|
| Lung Adenocarcinoma             | Glioblastoma Multiforme |
| Lung Squamous Cell<br>Carcinoma | Sarcoma                 |
| Pancreas Adenocarcinoma         | Melanoma                |
| Prostate Adenocarcinoma         | Breast Carcinoma        |

### **Observed Cancer-Specific Immune Protection (1/2)**

In challenging mice 4 months after treatment, those previously treated by the Alpha DaRT displayed a meaningful retained protection against regrowth of the same tumor type, as compared to the two control groups



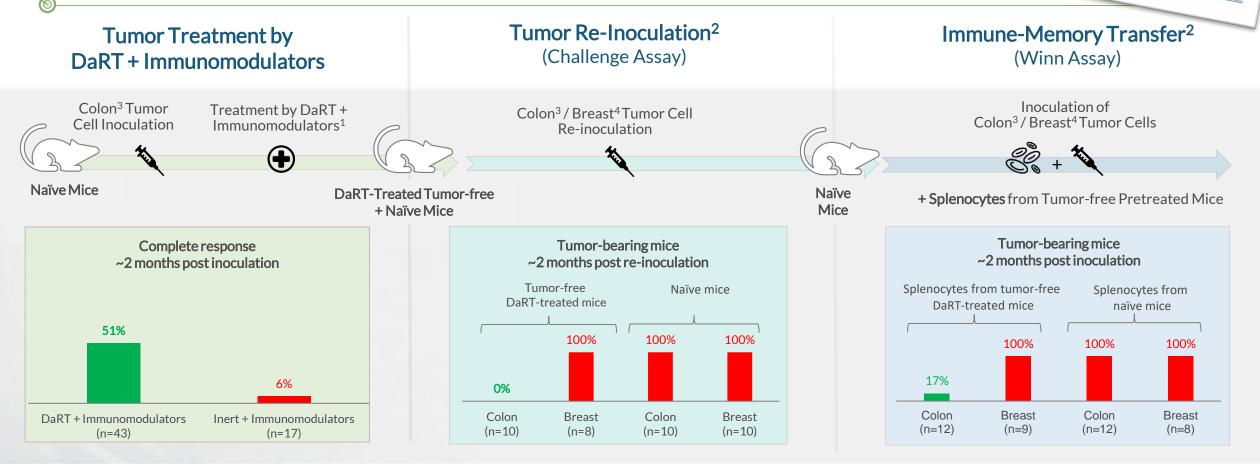
<sup>(1)</sup> Three groups of mice were inoculated with 5 x 10<sup>5</sup> CT26 tumor cells and then treated with (1) DaRT + CP, Sildenafil and 2xCpG, N=10 (2) DaRT + CP, Sildenafil and CpG, N=10 or (3) inert + CP, Sildenafil and 2xCpG, N=9. Complete responders or tumor-resected mice were re-challenged ~4 months after DaRT with 5 x 10<sup>6</sup> CT26 tumor cells.

(3) CT265 x 10<sup>6</sup>.

<sup>(2)</sup> CT265 x 10<sup>5</sup>.

### **Observed Cancer-Specific Immune Protection (2/2)**

This activity was then shown to be tumor-specific – the challenge only resisted regrowth of the same tumor line. It was also shown to be transferrable via the transfer of splenocytes



(1) Immuno-modulation refers to a combination of low dose CP, Sildenafil and CpG.

2) Mice with CR from DaRT + immuno-modulators (n = 18) and naïve mice (n = 20) were inoculated with 5 x 10<sup>5</sup> CT26 or DA3 cells 52 days post inoculation (Challenge Assay). Naïve mice were injected intradermally with splenocytes from either naïve or CT26-bearing mice treated by DaRT and immunomodulators, coupled with CT26 or DA3 tumor cells (Winn assay). The presented results are based on cumulative data from two different experiments.

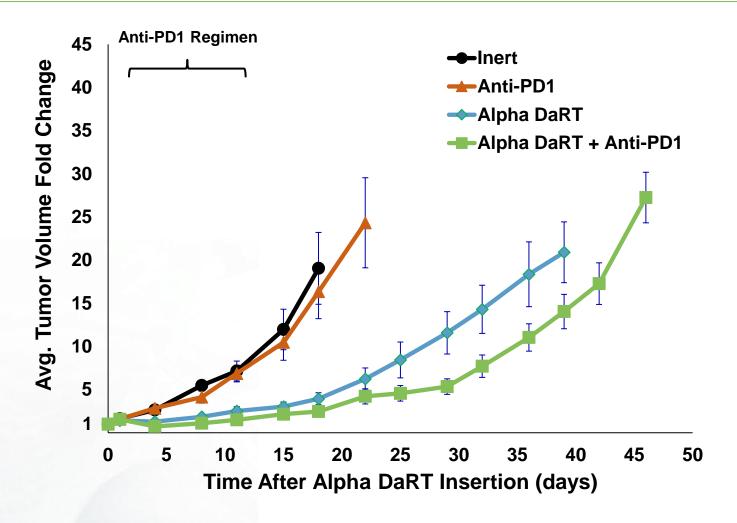
(3) CT265 x 10<sup>5</sup>.

(4) DA35 x 10<sup>5</sup>.

Combining alpha radiation-based brachytherapy with immunomodulators promotes complete tumor regression in mice via tumor-specific long-term immune response wird <u>Demakerich Adl Cohen Margalit Effatt Michael Schmidt Hans-Georg Rammensee Switt 5. Nac</u>

### Alpha DaRT Elicits Effect from anti-PD1 in SCC Mouse Model (SQ2)

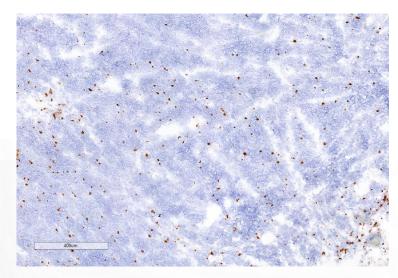
While mice with the SQ2 squamous cell carcinoma model showed little to no effect when treated with a murine anti-PD1 agent, the observed effect was larger for the combination with Alpha DaRT than for Alpha DaRT on its own



### Alpha DaRT Increases Infiltration of CD3+ T-cells Into the Tumor

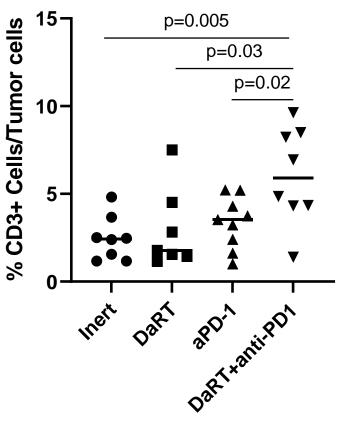
The combination of Alpha DaRT with anti-PD1 demonstrates the highest level of TILs in mice with SQ2 SCC tumors, potentially indicating an ability to potentiate the checkpoint blockade

anti PD-1



Alpha DaRT + anti PD-1

#### TILs in SQ2 tumors



AlpheTAU

### Outline of Our First Clinical Study: Skin / Head & Neck SCC

#### Primary objective: Evaluate feasibility & safety

Secondary objective: Evaluate initial tumor response & local progression-free survival

Key Eligibility Criteria

SCC histopathologically confirmed Lesions  $\leq 5 \text{ cm}^*$ Age  $\geq 18$ ECOG performance scale  $\leq 2$ Patients W/O immunosuppression Generally previously treated by radiation or surgery, recurrent



**Treatment plan** based on CT-simulation

**Sources** 1cm length, 0.7mm diam.

Activity per source 2 µCi

Outpatient setting

Local anesthesia

Number of sources inserted: min

3, max 169

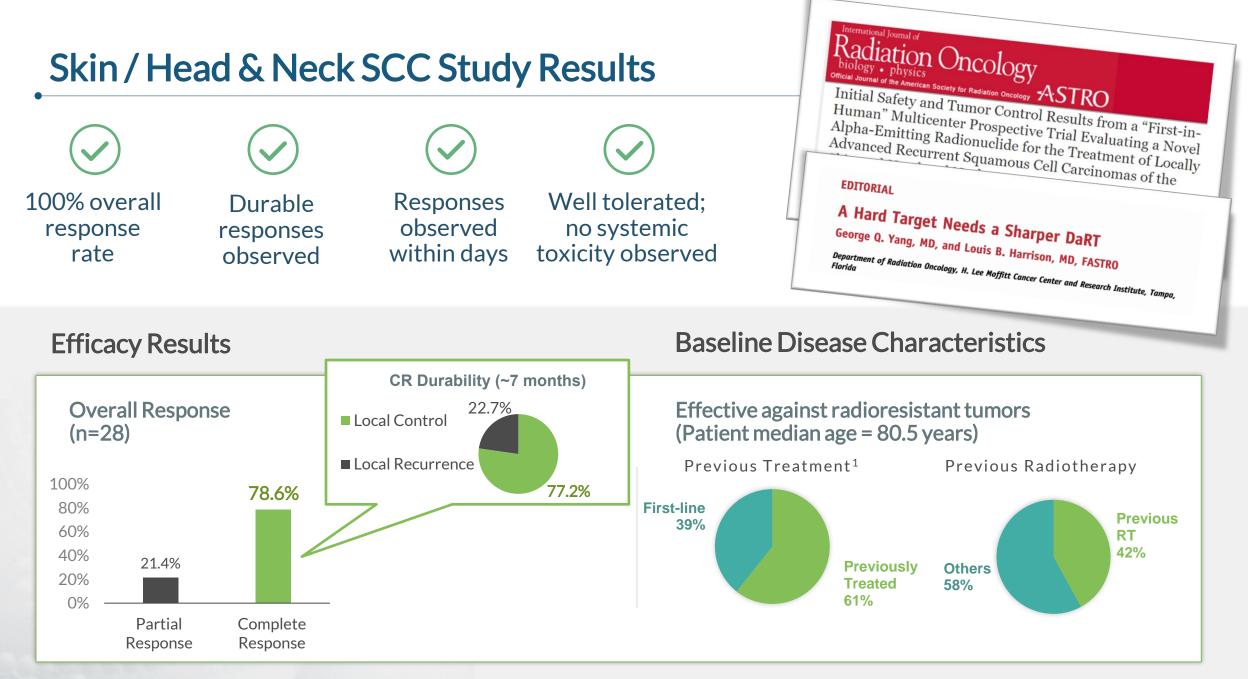




Alpha DaRT sources insertion
Removal after 15 days
Check-up on days 4, 9 and 30
after insertion
Long term follow up based on
standard of care

\*in the longest diameter (without nodal spread).

Trial Sites: Israel, Italy



<sup>1</sup>Most patients (60.7%) had recurrent and previously treated disease by either surgery, prior external beam radiotherapy or both; 13 of 31 (42%) had received prior RT.

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#### **AP-02 Complete Response**

| Age                                     | 80                 | Applicators used            | 6  |
|---|--------------------|-----------------------------|----|
| Previous treatments                     | Radiation, Surgery | Alpha DaRT sources inserted | 10 |
| Tumor initial volume [cm <sup>3</sup> ] | 1.4                | Total activity [µCi]        | 20 |



### AP-022 Complete Response

| Age                                     | 68   |
|---|------|
| Previous treatments                     | None |
| Tumor initial volume [cm <sup>3</sup> ] | 2.8  |

| Applicators used            | 12 |
|-----------------------------|----|
| Alpha DaRT sources inserted | 24 |
| Total activity [µCi]        | 48 |



### Alpha DaRT Treatment was Well Tolerated

No systemic toxicities and minimal (< grade 2) local toxicities observed to date



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#### **Targeted treatment**

Designed to spare neighboring healthy tissue



#### No systemic toxicity observed Negligible and short-term radioactivity in the patient's body



#### Minimal local toxicity observed

Minimal local toxicity with grade ≤2 resolved within a month



#### Safe procedure for caregivers

No special shielding required

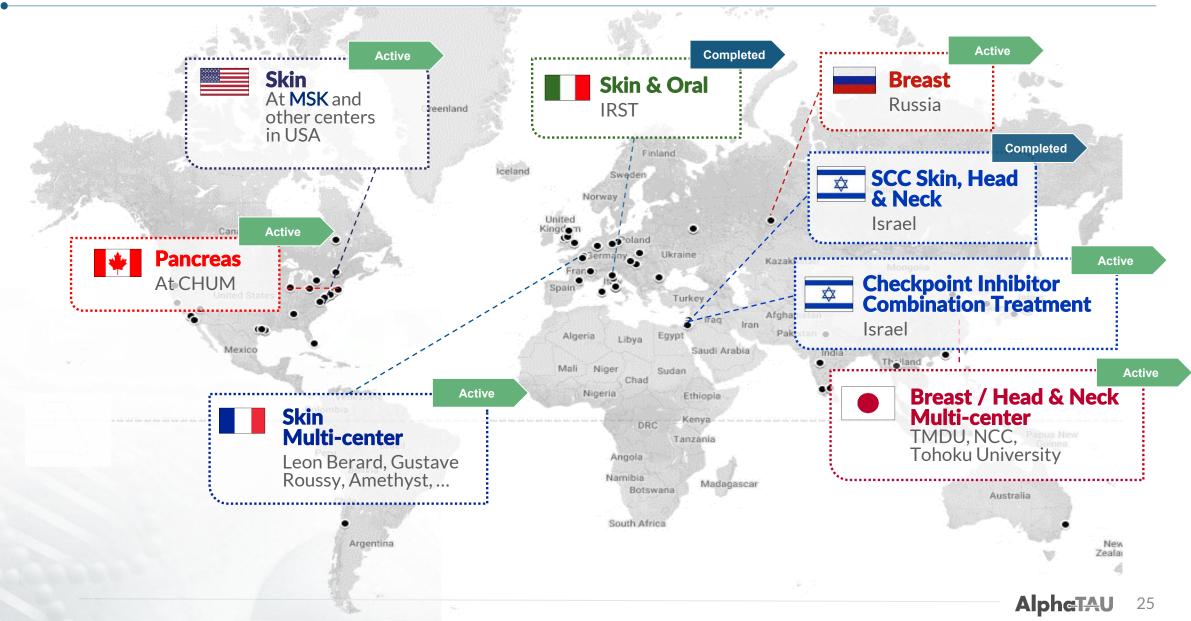


#### No suppression of immune system observed Critical in these times of pandemic

|   | Incidence (%)  |          |        |  |  |  |
|---|----------------|----------|--------|--|--|--|
| Acute Local                               | Severity Grade |          |        |  |  |  |
| Toxicity                                  | 1              | 2        | 3      |  |  |  |
| Administration site erythema              | 11 (41%)       | 9 (33%)  | 0 (0%) |  |  |  |
| Administration site edema                 | 9 (33%)        | 10 (37%) | 0 (0%) |  |  |  |
| Administration site pain                  | 8 (30%)        | 11 (41%) | 0 (0%) |  |  |  |
| Administration site exudate               | 2 (7%)         | 8 (30%)  | 0 (0%) |  |  |  |
| Administration site ulcer                 | 4 (15%)        | 5 (19%)  | 0 (0%) |  |  |  |
| Administration site numbness              | 1 (4%)         | 0 (0%)   | 0 (0%) |  |  |  |
| Administration site pruritus              | 3 (11%)        | 0 (0%)   | 0 (0%) |  |  |  |
| Administration site bleeding              | 1 (4%)         | 0 (0%)   | 0 (0%) |  |  |  |
| Aural myiasis<br>(administration<br>site) | 1 (4%)         | 0 (0%)   | 0 (0%) |  |  |  |
| Decreased appetite                        | 1 (4%)         | 0 (0%)   | 0 (0%) |  |  |  |

Potential Systemic Immune Effect Observed in One Patient Where Journal of Contemporary BRACHYTHERAPY a Second, Untreated Lesion Manifested CR **Complete Response + Potential Systemic Immune Effect** Case report Clinical evidence of abscopal effect in cutaneous 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 Untreated Tumors** After After Before Before 30-Nov-17 29-Dec-17 30-Nov-17 29-Dec-17

#### Seeds of Hope Worldwide – Selected Current Clinical Trials



### U.S. Pilot Feasibility Study – Trial Design

• FDA Breakthrough Device Designation received in June 2021

1

| Locations            | 5 centers in the US, led by Memorial Sloan Kettering Cancer Center   |
|----------------------|--|
| Treatment Timeframe  | H2 2021  |
| # of Patients        | 10   |
| Tumor Type           | Skin Cancers   |
| Primary Objectives   | Determine feasibility of delivering radiotherapy using Alpha DaRT, with successful delivery in at least 7 patients, and assess frequency and severity of acute AEs |
| Secondary Objectives | Assessments of radiotherapy-related AEs, tumor response, radiation safety, stability of device placement, and QoL  |
| Eligibility          | Malignant skin or superficial soft tissue tumor 1-5 cm in size that is suitable for percutaneous interstitial brachytherapy  |
|                      | AlpheTAU 26  |

### Case Study - 77 Y/O with Recurrent BCC on the Nose

Prior treatments:

Surgery (2005)

#### Tumor Size:

| Longest diameter            | 1.59 cm |
|-----------------------------|---------|
| Depth                       | 0.5 cm  |
| Volume                      | 0.65 ml |
|                             |         |
| Alpha DaRT Treatment:       |         |
| Applicators used            | 15      |
| Alpha DaRT sources inserted | 20      |
| Total activity [µCi]        | 40      |



#### Case Study - 77 Y/O with Recurrent BCC on the Nose

Results



#### U.S. Pilot Feasibility Study – Safety Results

- Twenty-two (22) **total adverse events** (AEs) were reported in 7 subjects
- Most AEs were of **mild or moderate severity**
- Two (2) serious AEs (SAEs) in a single subject both not related to study device or procedure

Number of Subjects with Procedure- or Device-Related\* Adverse Events by Severity Grade

#### Severity Grade

| Adverse Event                   | 1 | 2 | 3 |
|---------------------------------|---|---|---|
| Dermatitis radiation            | 2 | 1 | 0 |
| Localized edema                 | 1 | 0 | 0 |
| Joint range of motion decreased | 0 | 1 | 0 |
| Pain                            | 0 | 1 | 0 |
| Pruritis                        | 2 | 0 | 0 |
| Wound infection                 | 0 | 1 | 0 |
|                                 |   |   |   |

Note: Adverse events are presented according to CTCAE V5 coded terms. \* Probably or possibly related

All 10 subjects achieved a **complete response** (CR) at the 12-week follow-up visit

There were **no reported relapses** of disease by the final study visit at 24 weeks

#### Outline of Our Multicenter Pivotal Recurrent SCC study

- Primary / safety objectives:
- ORR based on Best Overall Response
- DOR 6 months after initial response
- Assess the safety based on statistics of device-related AEs (per CTCAE v5)

Secondary objectives: Evaluate O-DOR, local control, PFS and OS (all up to 12 months), and QoL Metrics

Key Eligibility Criteria



Recurrent non-metastatic cutaneous SCC

Patient with **no curative standard-ofcare options** No **previously untreated SCC** 

**Sample size** N = 86 patients

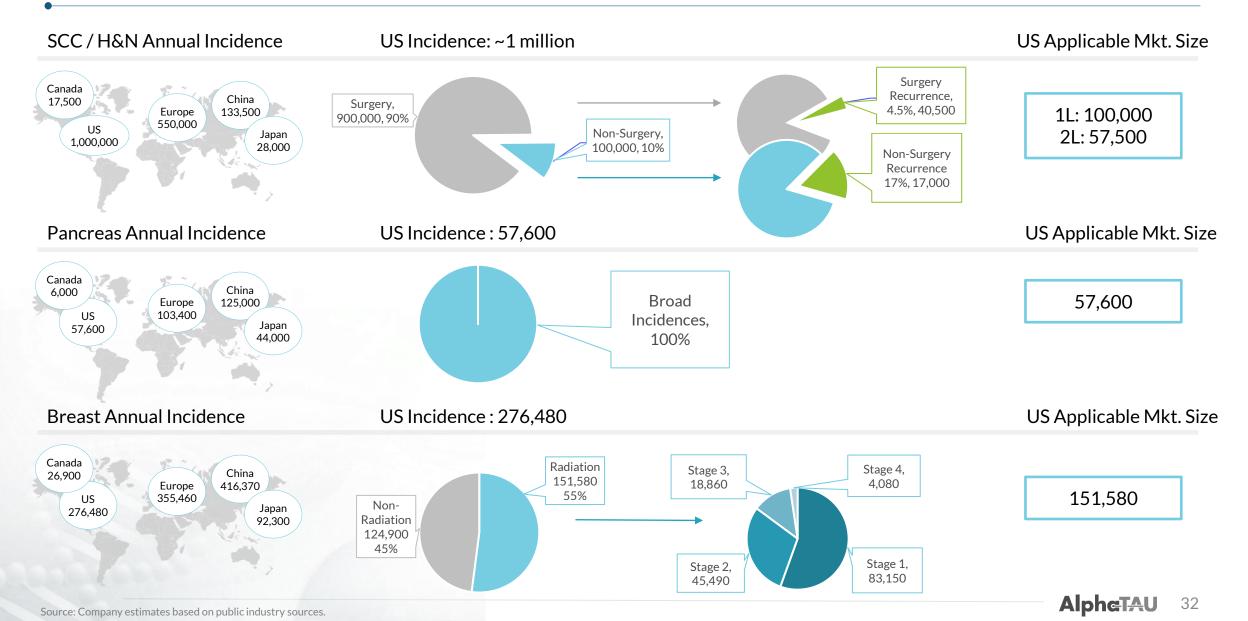
Treatment and Procedure

**Treatment plan** based on CTsimulation **Sources** 1cm length, 0.7mm diam. **Activity per source** 3 μCi **Local** anesthesia Timeline and Follow-Up



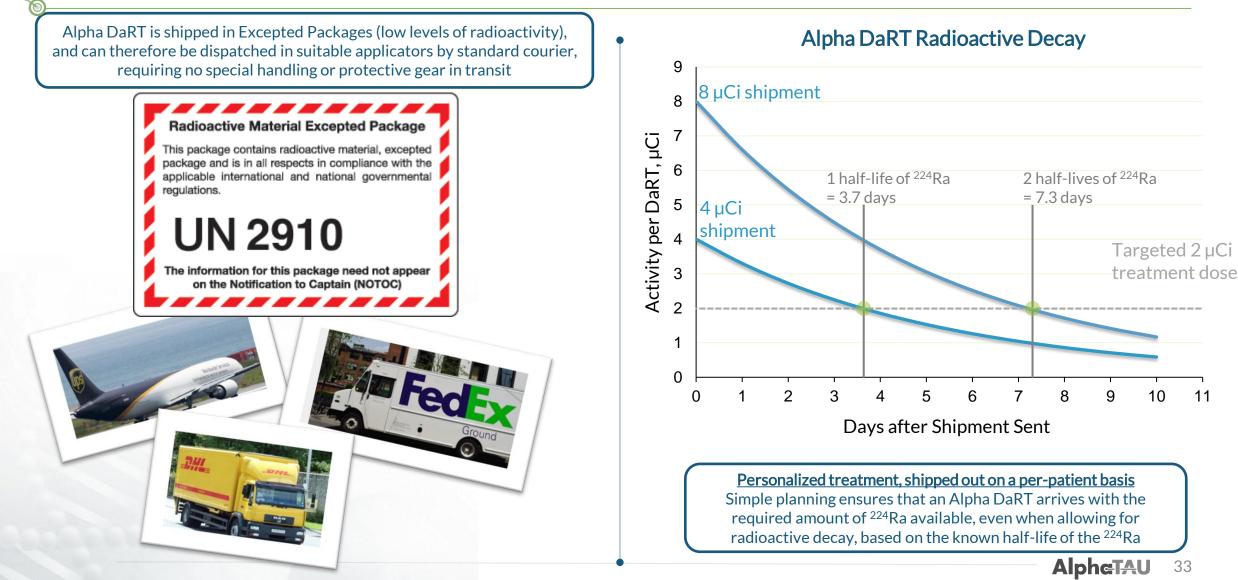
Alpha DaRT sources insertion Removal after 14 to 21 days Weekly follow-up during the treatment period

### Applicable Market Size – Estimates of Annual Incidence Data



### Simple Radioactive Supply Chain

Delivery does not require any special handling and simple planning ensures on-time arrival



### **Global Manufacturing Facilities**

ADS S

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



#### The Alpha Tau Executive Team

#### Strong management team with years of experience across the scientific and medical device space



10



**Uzi Sofer CEO & Chairman** 



**Raphi Levy Chief Financial** Officer



Prof. Itzhak Kelson **Chief Physics** Officer



**Prof. Yona** Keisari **Chief Scientific** Officer



**Robert Den, MD Chief Medical** Officer



**Amnon Gat Chief Operations** Officer

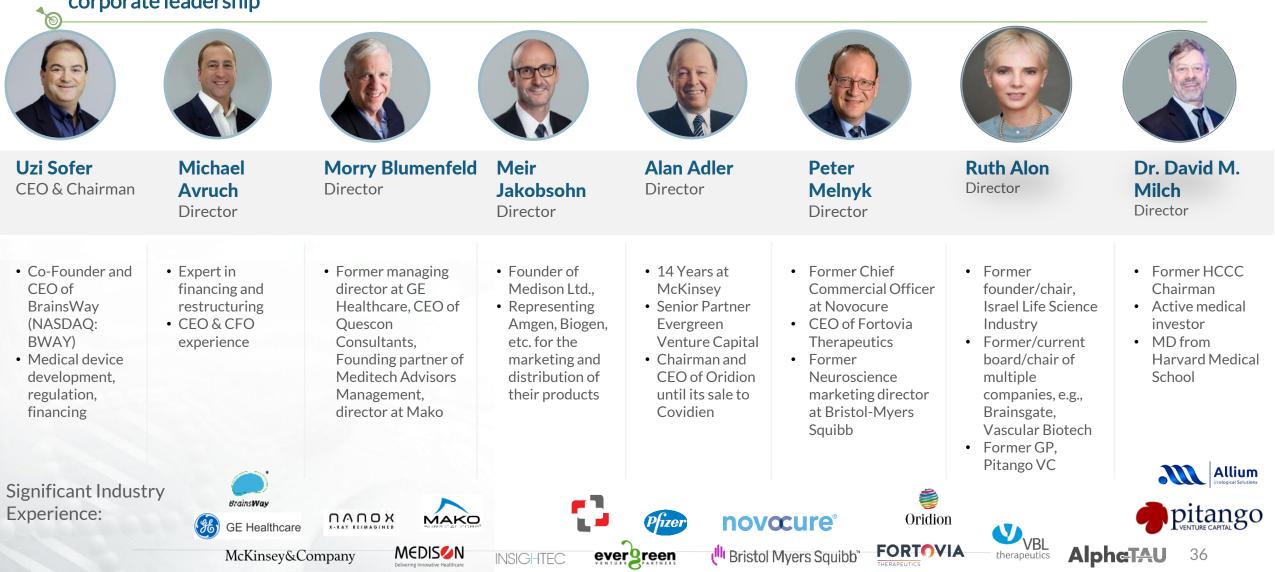


**Ronen Segal** Chief Technology Officer

- Co-Founder and CEO of BrainsWay (NASDAQ: BWAY)
- Medical device development. regulation, financing
- Former executive director in charge of healthcare investment banking in **Goldman Sachs** Israel
- Co-inventor of DaRT technology
  - Emeritus professor of physics (taught at Tel Aviv University, Yale University, Weizmann Institute etc.)
- Co-inventor of DaRT technology
- Professor of Immunology and Microbiology at Tel Aviv University, former NCI Post Doc Fellow
- Radiation oncologist and Associate Professor at Thomas Jefferson University Hospital
- Medical degree from Harvard Medical School
- >20 vears experience in medical devices and healthcare
- Marketing strategy specialist
- >20 years of top leadership roles, including medical device industry
- Chairman of the BSMT Consortium

### **Board of Directors**

Diverse mix of cancer therapeutic, medical device and financial expertise providing value-added oversight and guidance to corporate leadership



#### **Continued Track Record of Execution**

|   | Construction<br>Jerusalem<br>manufactur<br>facility |  | First<br>patient<br>treated in<br>the US | Completion<br>of<br>enrollment<br>in US pilot<br>study                      | First patient<br>treated in<br>combination<br>with<br>Keytruda | 100% CR<br>rate in US<br>pilot study                           | Completior<br>merger with<br>HCCC |   | First patient<br>treated in<br>prostate<br>cancer trial              |
|---|---|--|--|---|--|--|-----------------------------------|---|--|
| <b>O</b> Aug-20   | <b>O</b> Dec-20                                     | <b>O</b> Jun-21  | <b>O</b> Jul-21                          | <b>0</b> Oct-21   | <b>O</b> Nov-21  | <b>O</b> Jan-22  | <b>O</b> Mar-22                   | O May-22                                      | O Jun-22   |
| Israeli<br>marketing<br>approval for<br>SCC of the<br>skin & oral<br>cavity |   | Breakthro<br>Device<br>Designati<br>Alpha Dal<br>in skin and<br>cavity | on for<br>RT in SCC                      | Breakthroug<br>Device<br>Designation<br>the Alpha Da<br>in recurrent<br>GBM | for<br>aRT   | Completion<br>Japanese h<br>& neck pivo<br>trial<br>recruitmen | ead<br>otal                       | Launch of<br>French<br>Multi-<br>Center Trial | Receipt of<br>Conditional IDE<br>from FDA for<br>US Pivotal<br>Study |

### **Anticipated Milestones**

| Geography | Indication  | 2H 2022   | 1H 2023                                      | 2H 2023  |  |
|-----------|---|---|--|--|--|
| North     | Recurrent Cutaneous<br>SCC (United States)          | First patient treated in multi-center pivotal trial         |  | Completion of multi-center pivotal trial recruitment |  |
| America   | Pancreatic Cancer<br>(Canada)<br><i>(Tentative)</i> | First patient in feasibility trial                          | Interim read-out of<br>feasibility trial     |  |  |
| leveel    | Prostate Cancer                                     |   | Read-out of<br>prostate<br>cancer trial data |  |  |
| Israel    | Pancreatic Cancer                                   | Initiate feasibility<br>trial                               |  |  |  |
| Japan     | Head & Neck SCC                                     | Potential submission<br>of pivotal trial for<br>PMDA review | Potential PMDA approval                      |  |  |

# **AlpheTAU** Saving Lives Globally

