# NE©IMMUNETECH Expanding the Immuno-Oncology Frontier & Beyond

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## NeoImmuneTech: Expanding the Immuno-Oncology Frontier and Beyond

#### The Company (www.neoimmunetech.com)

- Founded in 2014; based in Rockville, Maryland
- Quickly expanding in personnel and operations
- Successful IPO (KOSDAQ: 950220) on March 16, 2021

#### The Lead Asset

- NT-I7 (efineptakin alfa)\* is a long-acting IL-7 uniquely positioned to address unmet medical needs in Immuno-Oncology and other therapeutic areas
- IL-7, a fundamental cytokine for lymphocyte development and survival, can enhance immunity to cancer as well as infectious diseases
- Early clinical efficacy signals in three immune cold tumors: MSS CRC, PanCa, and GBM

#### The Management Team

- Led by scientific founder, who invented NT-I7
- Senior management team complemented by executives with rich industry experiences (Novartis, BMS, Pfizer, Eli Lilly, GSK, AstraZeneca, PwC, etc.)
- · Seven decades of combined scientific, clinical, and business experience in drug development



#### Ne©Immune

## IL-7: A Fundamental Cytokine for Lymphocyte Development & Survival



### NT-I7 Overcomes the Key Limitations of IL-7

## The only clinical-stage long-acting human IL-7



#### Production yield up to 126-fold





## Unique Biology Enables Strong NT-I7 Positioning in Immuno-Oncology



## Early Clinical Efficacy Signals In Three Immune Cold Tumors

- In both MSS CRC and PanCa, where no response is expected for pembro alone
  - 3 (18%) out of 17 evaluable MSS CRC pts treated with NT-I7+pembro achieved PR by iRECIST, including one PR by RECIST 1.1
  - One PR by RECIST 1.1 was observed in 17 evaluable pancreatic cancer (PanCa) pts
  - In PanCa, followup was too short for iPR in most patients
- Responses, once occurred, are durable and continue to deepen over time
- The combination treatment of NT-I7 + pembrolizumab was well tolerated with low number of grade 4 (2/51) and no grade 5 drug related AEs
- Favorable PFS and OS were also observed in NT-I7 treated high-grade gliomas (HGG) patients after chemoradiotherapy

## Clinical Response in MSS CRC: Waterfall Plot

Among the 17 evaluable patients:

- The overall response rate (ORR) was 18% per iRECIST and 6% per RECIST v1.1
- ✤ The disease-control rate (DCR) was 59% per iRECIST and 53% per RECIST v1.1



*Note*: One patient's target lesion became not evaluable at the follow-up scans; this patient had progression on non-target lesion at 1<sup>st</sup> follow-up scan

**#** Patient achieved a **confirmed PR** with -**56%** tumor reduction at the 3<sup>rd</sup> follow up.

#### Pseudo-progression was observed in two patients:

\* Patient had SD at the 1<sup>st</sup> follow up, then developed new lesion at the 2<sup>nd</sup> follow up, however, tumor reductions in the follow up scans were continuously observed and reached -30% at the 4<sup>th</sup> follow up.

\*\* Patient had PD (+20%) at the 1<sup>st</sup> follow up, then had continuous tumor reductions and achieved **confirmed PR** with -**58%** tumor reduction at the 5<sup>th</sup> follow up.

as of November 10, 2021

## 3 patients with partial response per iRECIST

## Pseudo Progression in MSS CRC

Pseudo progression may be attributed to small number of tumor-reactive T cells proliferating, in presence of NT-I7, to sufficient quantity for clinical response over time





Representative CT scans from the patient with CPI-naïve R/R advanced MSS-CRC that had a PD at the 1st assessment and then achieved confirmed PR with -58% of tumor reduction in the subsequent scans

#### **Clinical Response in MSS CRC: Swimmer Plot**

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#### 3 patients with partial response per iRECIST

Swimmer plot for the treatment duration (weeks) and response of individuals with CPI-naïve R/R MSS-CRC. The median treatment duration was 24.14 weeks. Objective response rate (ORR) was achieved in 3 (18%) out of 17 evaluable patients per iRECIST and 1 (6%) out of 17 evaluable patients achieved confirmed PR per RECIST v1.1. Disease control rate (DCR) was observed in 10 (59%) out of 17 evaluable patients per iRECIST and 9 (53%) out of 17 evaluable patients by RECIST v1.1.

As of November 10, 2021, the median treatment duration was 24.14 weeks

#### **Clinical Response in PanCa: Swimmer Plot**



#### Duration of Treatment (Weeks)

Swimmer plot for the treatment duration (weeks) and response of individuals with CPI-naïve R/R pancreatic cancer. The median treatment duration was 11.71 weeks. Objective response rate (ORR) was achieved in 1 (6%) out of 17 evaluable patients per iRECIST and RECIST v1.1. Disease control rate (DCR) was observed in 5 (29%) out of 17 evaluable patients per iRECIST and RECIST v1.1.

As of November 10, 2021, the median treatment duration was 11.7 weeks.

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## Confirmed PR With 72% Tumor Reduction



Sum of target lesions

CT scans from the subject with CPI-Naïve R/R advanced PC who achieved a PR. A durable tumor reduction was observed after the treatment of NT-I7 and pembrolizumab.

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## Favorable PFS and OS in NT-I7 treated HGG patients



# **The Science Behind NT-I7**

- Based on the response dynamics and IL-7 biology, we hypothesize that NT-I7 works by stimulating a subset of T cells to proliferate and attack tumors
  - In immune cold tumors, the number of these T cells may be too low for PD1 blockade alone to show clinical responses
  - In presence of NT-I7, these T cells proliferate to sufficient numbers over time for clinical responses
  - As a result, once responses occur, it can persist and continue to deepen
  - In immune "hot" tumors where there are more tumor reactive T cells, NT-I7 may expand and deepen responses to aPD1/PDL1 therapy broadly
- Consistent with this hypothesis, we see not only increased T cell infiltration in the tumor microenvironment but also a dramatic increase of stem-cell memory CD8+ T cells (Tscm) in the blood
  - This dramatic increase of Tscm was observed in patients receiving NT-I7 alone (in high grade glioma pts) as well as NT-I7+pembro (MSS CRC and pancreatic cancer pts)



## Differential Increase of $T_{SCM}$ in NT-I7 Treated Cancer Patients

**Stem-cell memory CD8+ T cells** (**T**<sub>SCM</sub>) have *self-renewal capabilities* and have shown *better antitumor activity* compared to other memory subsets



While CD8+  $T_{SCM}$  increased by 50x, the other CD8+ T cell subsets only increase by ~5x. The differential increase of the CD8+  $T_{SCM}$  subset could be part of the mechanism of action of NT-I7



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#### NT-I7 Significantly Increased **CD8+ T<sub>SCM</sub>** in HGG patients Treated with Chemo/RT



Key eligibility: HGG requiring RT/TMZ; ALC  $\geq$  600 cells/mm3 *Primary objective*: maximal tolerated dose (MTD)

Dose Level	NT-I7 Dose
1	60 µg/kg
2	120 µg/kg
3	240 µg/kg
4	540 µg/kg
5	720 µg/kg
6	960 µg/kg

ALC in All Doses



Campian et al., SITC 2021 & SNO 2021 16

## NT-I7 Enhanced Lymphocyte Infiltration in MSS CRC and PanCa Patients

**Tumor-infiltrating lymphocytes** (**TILs**) were quantified from pre- and post-treatment (W5) biopsies. Results are shown as frequency of stromal cells that are lymphocytes.



Patients with **objective response** showed enhanced **TIL** infiltration

<sup>1</sup>*Kim et al., SITC 2021 & <sup>2</sup>Naing et al., SITC 2021* 17

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# **Realize Large Business Opportunities**

## NT-I7 Strategic Opportunities in Immuno-Oncology

#### **Business Opportunities**

#### Immune Cold Tumor: >\$15B/yr

- "Holy grail" for novel I-O MOAs; high risk high return
- Include 3 of the 4 large tumors types (MSS-CRC, prostate and other breast cancers)

#### PD(L)1 Progressors: >\$15B/yr

- Low efficacy bar; limited competition; fast to market possibility
- Large business opportunity due to PD1/L1 adoption
- PD(L)1 Naïve Patients: >\$30B/yr
  - Much bigger opportunity but higher efficacy bar to enter
  - Need to compete with multiple PD1 combos (chemo, VEGF, etc)

#### NT-I7 Study/Data

- Immune Cold Tumors (PD1 naïve)
  - Efficacy signal in three immune cold tumors (MSS CRC, PanCa, and HGG)
  - Provocative data in MSS CRC

#### PD(L)1 Progressors

- NT-I7 + Pembro in CPI-treated NSCLC, SCLC, TNBC, OVA
- NT-I7 + Atezo in CPI-treated skin cancers
- PD(L)1 Naïve Patients
  - NT-I7 + Atezo in 1L NSCLC

## Broad Therapeutic Potential of NT-I7

#### Immuno-Oncology

- Checkpoint combination in immune hot and cold tumors (focused effort; ongoing trials)
- CAR-T and TCR-T combinations (ongoing trial)
- T cell engager combinations
- Combinations with cancer vaccines, other cytokines, chemo, radiation therapies, etc.

#### **Infectious Diseases**

- Infections associated with cancer therapies (ongoing trial)
- Covid-19 (ongoing trials)
- Influenza/pneumonia
- Vaccine enhancement
- Sepsis

#### **Immune Reconstitutions**

- Acute radiation syndrome (ongoing study)
- Bone marrow transplantations (including stem cell mobilization)
- CAR-T and TCR-T combinations (ongoing trial)

## **Realize Large Business Opportunities**

- NT-I7 (efineptakin alfa)\* is a long-acting IL-7 uniquely positioned to address unmet medical needs in Immuno-Oncology and other therapeutic areas
- Early clinical efficacy signals in three immune cold tumors: MSS CRC, PanCa, and GBM
- Strengthen clinical dataset
  - Longer followup on more patients with MSS CRC and PanCa
  - Continue to investigate in other immune cold and hot tumors
  - Evaluate patient selection strategy to further enrich responding patients

