



### Arming the immune system to fight cancer

**Capital Markets Update** 

June 26th 2017



### Important notice and disclaimer

This report contains certain forward-looking statements based on uncertainty, since they relate to events and depend on circumstances that will occur in future and which, by their nature, will have an impact on the results of operations and the financial condition of Targovax. Such forward-looking statements reflect the current views of Targovax and are based on the information currently available to the company. Targovax cannot give any assurance as to the correctness of such statements.

There are a number of factors that could cause actual results and developments to differ materially from those expressed or implied in these forward-looking statements. These factors include, among other things, risks or uncertainties associated with the success of future clinical trials; risks relating to personal injury or death in connection with clinical trials or following commercialization of the company's products, and liability in connection therewith; risks relating to the company's freedom to operate (competitors patents) in respect of the products it develops; risks of non-approval of patents not yet granted and the company's ability to adequately protect its intellectual property and know-how; risks relating to obtaining regulatory approval and other regulatory risks relating to the development and future commercialization of the company's products; risks that research and development will not yield new products that achieve commercial success; risks relating to the company's ability to successfully commercialize and gain market acceptance for Targovax's products; risks relating to the future development of the pricing environment and/or regulations for pharmaceutical products; risks relating to the company's ability to secure additional financing in the future, which may not be available on favorable terms or at all; risks relating to currency fluctuations; risks relating to the company's ability to retain key personnel; and risks relating to the impact of competition.



### **Capital Markets Update - Agenda**

- Introduction CEO, Øystein Soug
- Targovax's technology and trials CMO, Dr Magnus Jäderberg
- A physician's view on pancreatic cancer *Prof Daniel Palmer*
- Financial update *CFO, Erik Wiklund*
- O Q&A



## Targovax develops two novel cancer immunotherapy drugs – both with promising phase I/II data

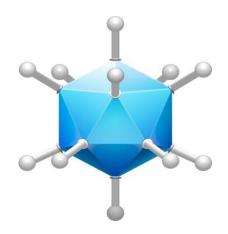
## ONCOS-102 Oncolytic virus

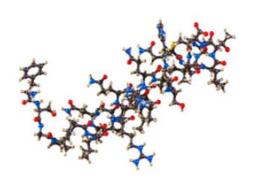
- Injected into the tumor
- Releases antigens
- Stimulates "killer" white blood cells (T-cells)

#### **TG01**

Cancer vaccine

- Therapeutic vaccine
- Mimics antigens
- Stimulates "killer" white blood cells (T-cells)





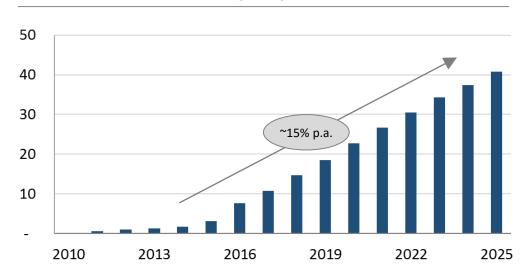


## Immunotherapy is considered to have enormous potential, and the market is expected to reach 30-50b USD by 2025



Science, December 2013

#### Estimated market size (\$Bn)\*

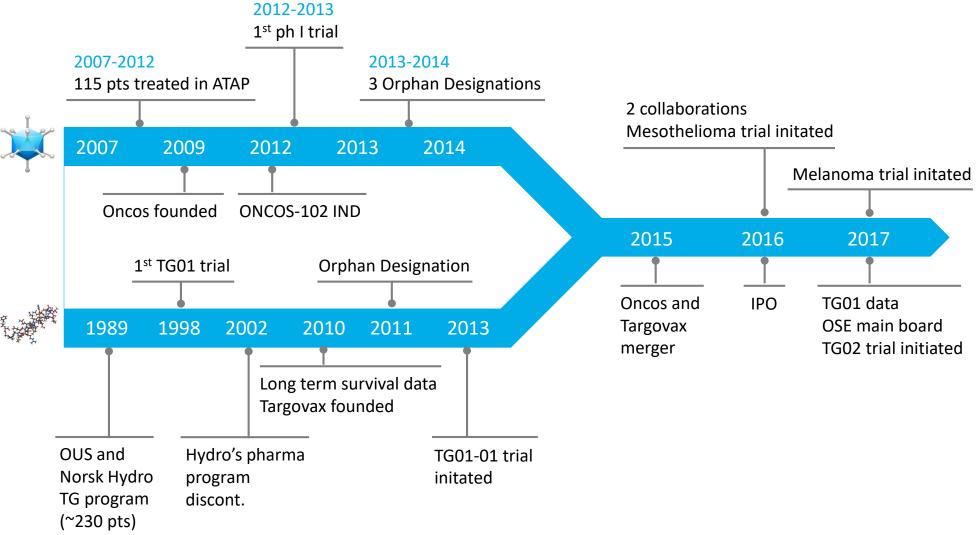


- o 8 products currently on the market
- Market estimated to reach 40b USD in 2025
- Estimated that 2/3 of cancers will be treated with immunotherapy by 2025



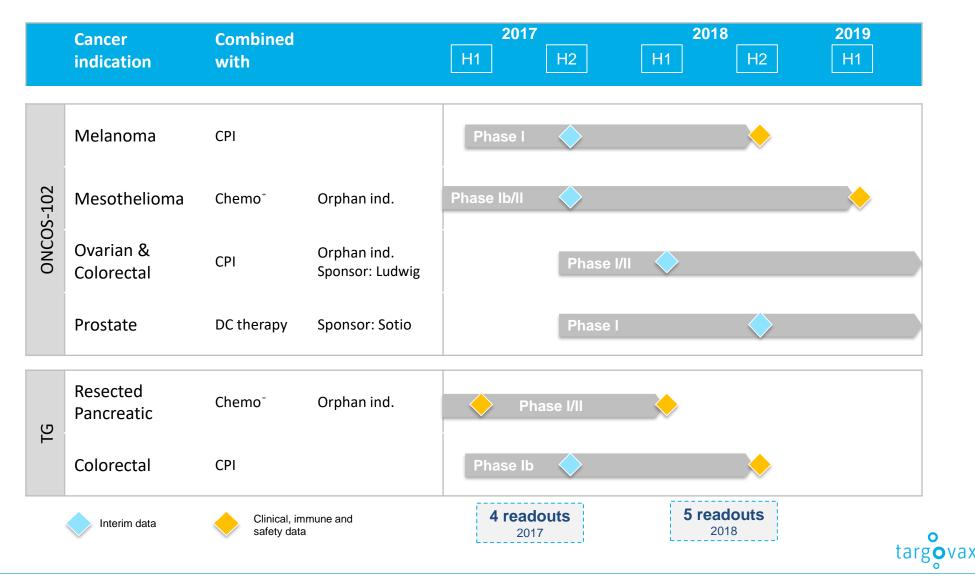
<sup>\*</sup> Citi Research, Barclays Capital, Leerink Swann, BMO Capital Markets

### **Targovax history**





## Two platforms and six clinical trials in total ensures a diversified program with frequent data readouts



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- Introduction to immunotherapy
- ONCOS-102 oncolytic virus platform
- TG RAS-peptide vaccine platform
- Targovax clinical program overview



### Immunotherapy is revolutionizing the way we treat cancer, in some cases curing previously thought incurable patients

Case example – Patient in a Yervoy checkpoint inhibitor trial



**Prior to Yervoy\*** 



4 weeks



8 weeks



20 weeks



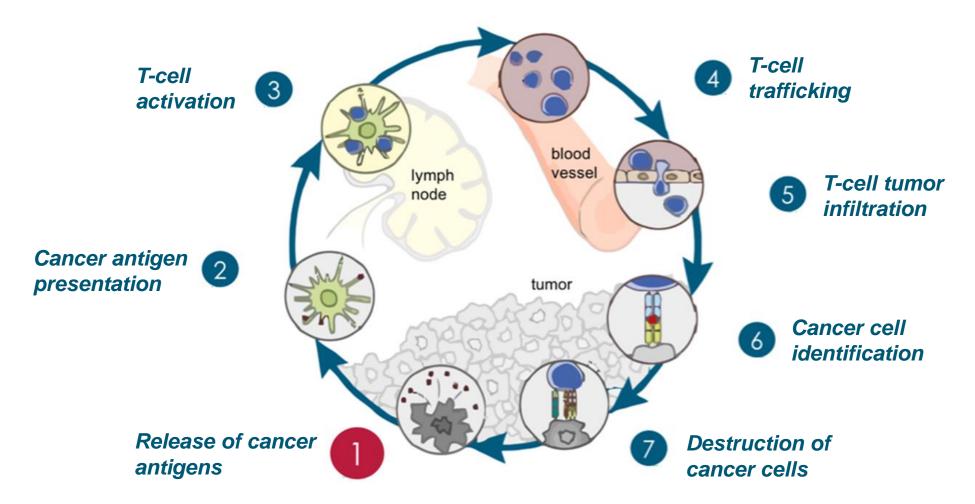
8 months



1 year

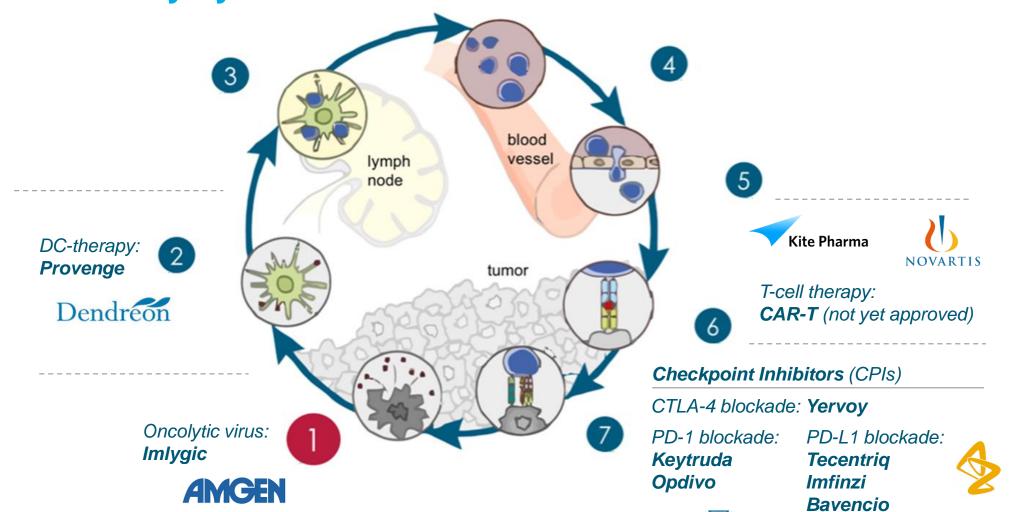


## The aim of cancer immunotherapy is to boost the natural cancer immunity cycle





Immunotherapies target different aspects of the cancer immunity cycle



www.targovax.com

**Bristol-Myers Squibb** 

Roche

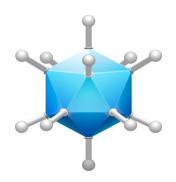
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**MERCK** 

## Targovax is developing two novel proprietary immunotherapy platforms, with promising phase I/II data

## ONCOS-102 Oncolytic virus

- Genetically tailored Adenovirus
- Selectively infects and lyses cancer cells
- Releases cancer antigens
- Triggers immune response



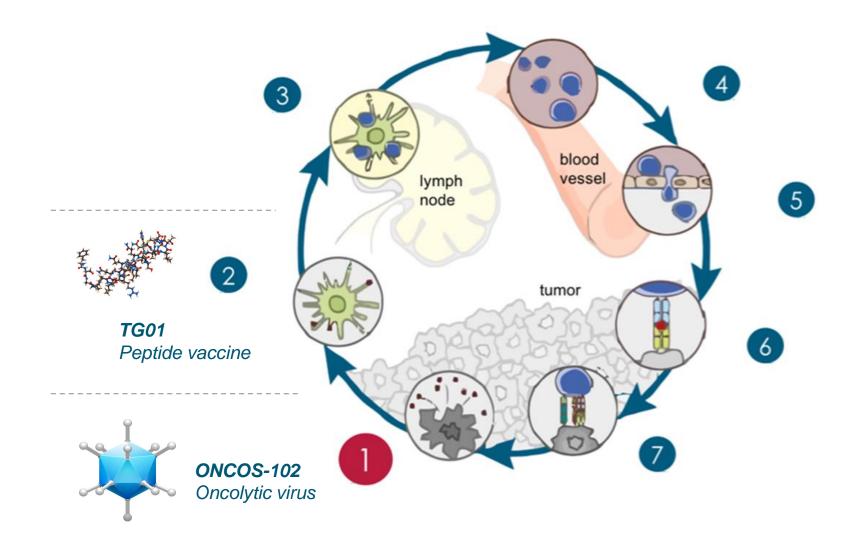
## **TG01**Peptide vaccine

- Cocktail of 7 synthetic peptides mimicking clinically relevant RAS mutations
- Generates RAS-specific T-cells
- T-cells kill cancer cells displaying mutated RAS antigens on their surface





## TG01 and ONCOS-102 have distinct targeting mechanisms in the cancer immunity cycle



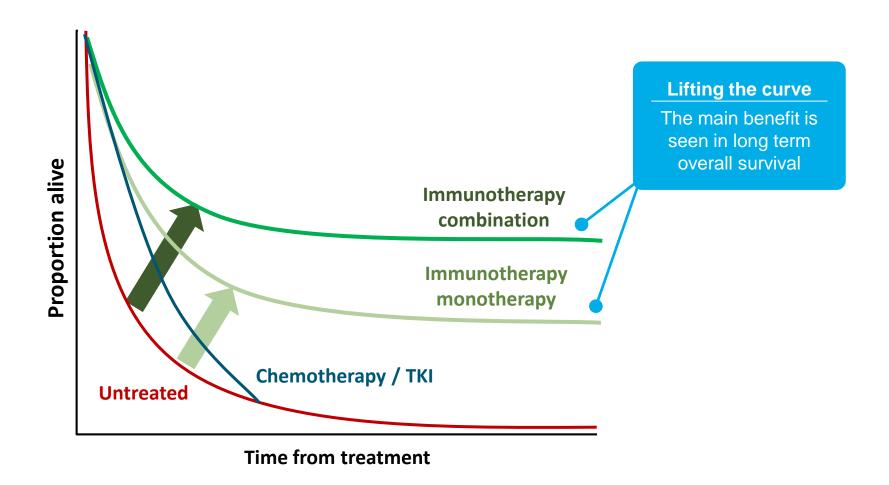


## By combining immunotherapies multiple aspects of the cancer immunity cycle can be modulated in parallel

Immuno-oncology mechanisms		Wake up the immune system	Train cancer specific T-cells	T-cells attack the cancer	Disarm cancer defence
Car analogy		Ignite engine	Switch on GPS– targeting	Press the gas pedal	Release brakes
	ONCOS-102 – Oncolytic virus		<b>√</b>	<b>√</b>	_
	TG 01 – Peptide vaccine			<b>√</b>	-
Kite Pharma	Peptide viral vaccine T-Cell therapy (CAR)				_
MERCK AstraZeneca  Genentech  Bristol-Myers Squibb  EMD Serono  Pfizer	Check point inhibitors (CPIs)	-	_	_	<b>√</b>



## The goal is to turn cancer into a manageable chronic disease by combining immuno-oncology therapies





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## ONCOS-102 works by making cancer antigens visible to the immune system, thus generating tumor specific T-cells

#### Activate immune system:

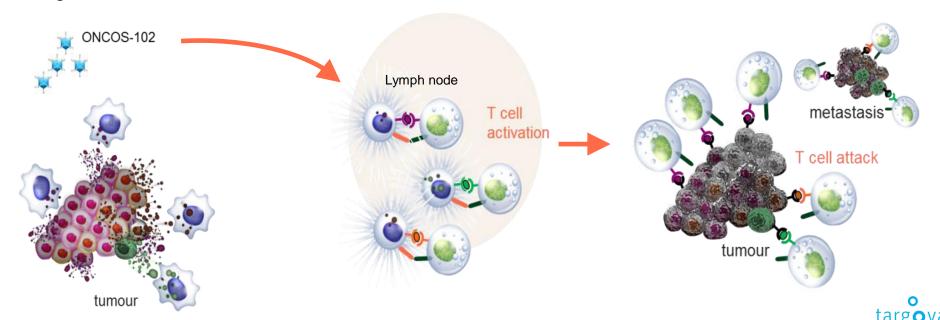
- Virus injected directly into the tumor / peritoneum
- Infected cells lyse and release cancer-specific antigens
- Immune system picks up antigens

#### Train T-cells:

- APCs present tumor specific antigens at lymph nodes
- Production of tumor specific T-cells

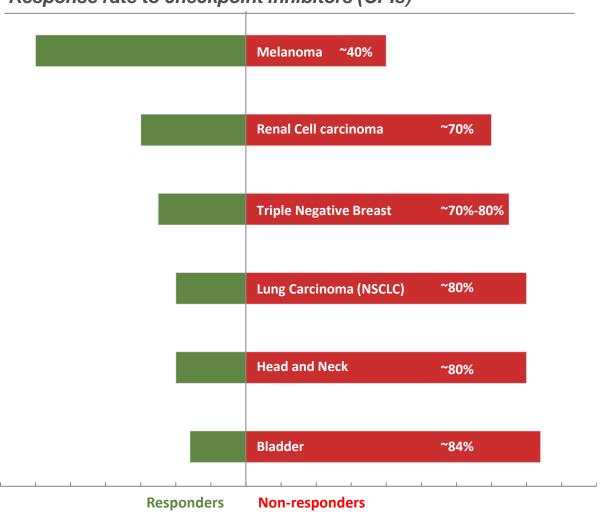
#### Attack the cancer:

- Tumor specific T-cells circulate in the body
- Identify lesions and kill the cancer cells



### Most patients do not respond to check point inhibitors (CPIs), due to lack of T-cells in the tumor microenvironment

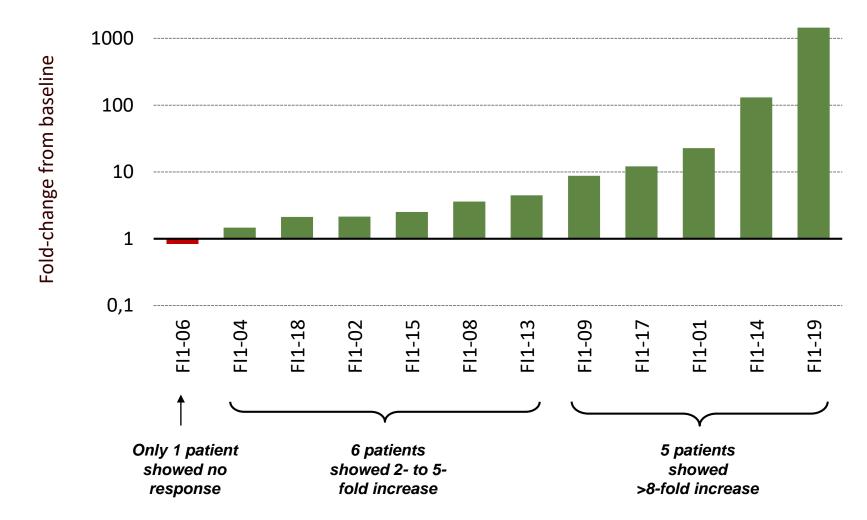
Response rate to checkpoint inhibitors (CPIs)



Complimentary immune priming medicines may make tumors respond better to checkpoint inhibitors



## ONCOS-102 phase I: Increased tumor infiltrating CD8+ T-cells in 11 of 12 cancer patients with a range of solid tumors





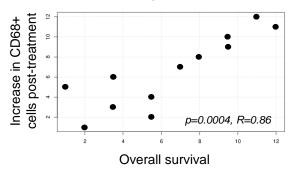
## In the initial Phase I ONCOS-102 trial tumor specific and systemic immune response was observed

**Evidence that immune system** recognizes tumor threat

Innate Immune System (biopsy)

- Induction of proinflammatory cytokines + fever (all patients)
- Infiltration of innate immune cells into tumors in 11 out of 12 patients

#### Scatterplot of ranks



Correlation between post-treatment increase in innate immune cells and OS

**Evidence that T-cells find the tumor and are cell killing** 

Adaptive immune system (biopsy)

- Increase in T-cell infiltration into tumors (including CD8+ killer T-cells) in 11 out of 12 patients
- Observation in one non-injected distant metastasis

OvCa. patient (FI1-19)





Correlation between post-treatment increase in CD8+ T-cells and OS

**Evidence of production of tumor antigen specific T-cells** 

Anti-tumor immune response (blood)

 Systemic induction of tumor-specific CD8+ T-cells

#### Ovarian patient:

NY-ESO-1, MAGE-A1, MAGE-A3, and Mesothelin specific CD8+ cells

#### Mesothelioma patient:

MAGE-A3 specific CD8+ cells

Associated with clinical benefit



## The encouraging Phase I results have triggered the initiation of a broad ONCOS-102 clinical program consisting of four new trials

Compassionate use program
Finland

115 patients

- Testing within ATAPEU program
- Individual clinical responses
- Reassuring safety data

Initial Phase I trial
Solid tumors
7 indications

- 12 refractory patients
- ONCOS-102 monotherapy
- Correlation between immune activation and survival

Melanoma
Phase I
12 patients

- Combination with PD-1
   CPI in refractory patients
- Proof-of-concept
- Memorial Sloan Kettering

Mesothelioma
Phase I/II - controlled
30 patients

- Combination with chemo
- Randomized controlled trial
- Ultra-orphan indication

Ovarian / colorectal Phase I/II - controlled 78 patients

- Collaboration with Ludwig & CRI
- Combination with Medimmune's durvalumab
- Randomized controlled trial

Prostate
Phase I
10 patients

- Partnered with Sotio
- Combination with DC therapy



### Melanoma trial – will CPI refractory patients start responding after immune-priming with ONCOS-102?

#### Setting

- Advanced malignant melanoma patients not responsing to CPIs
- Immune activate patients with ONCOS-102, then re-challenge with a CPI (Keytruda@)

#### Site

- 12 patients
- Memorial Sloan Kettering Cancer Centre

#### Key endpoints

- Safety
- Immune activation
- Clinical response data

#### Sequence

ONCOS-102 - 3 weeks

Keytruda – 5 months

Proof-ofconcept

Will CPI refractory melanoma patients start responding to Keytruda after challenge by ONCOS-102?

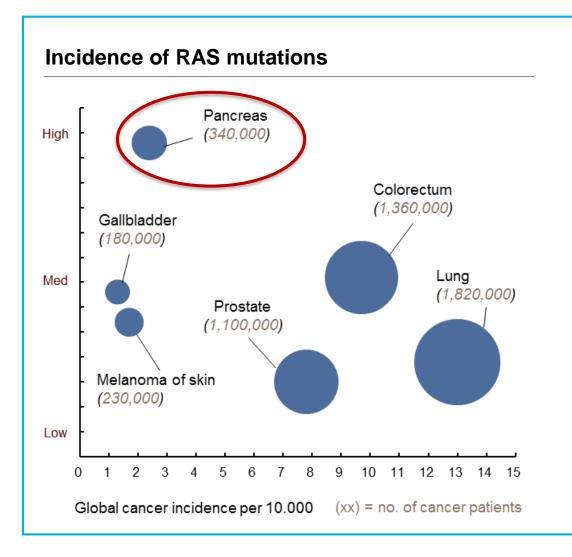


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## RAS is a key regulator of cell cycle that is mutated in 20-30% of all cancer patients, and >85% of pancreatic cancers



- One of the most common mutations in cancer
- RAS is one of the most well-defined neoantigens
- Results in cell division permanently switched on
- No existing therapies targeting RAS
- Occurs in >85% of pancreatic cancer patients



## The TG peptides prime the immune system to recognize and destroy RAS mutated cancer cells

#### Activate immune system:

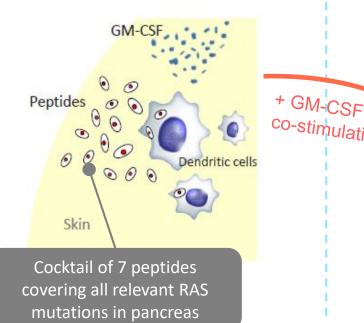
- TG peptides injected into the skin with GM-CSF adjuvant
- APCs pick up the TG RAS antigens

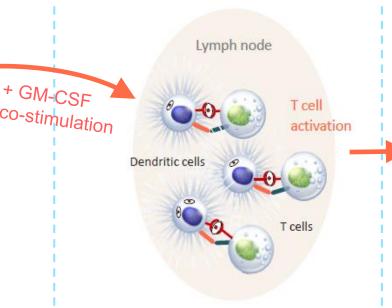
#### Train T-cells:

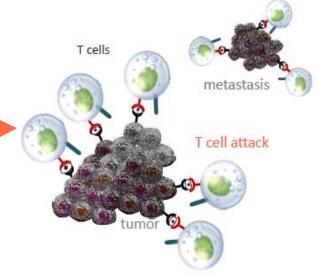
- APCs migrate to lymph nodes and present RAS specific antigens
- Production of RAS specific T-cells

#### Attack the cancer:

- RAS specific T-cells identify mutated RAS antigens on cancer cell surface
- Killer T-cells destroy the cancer cells



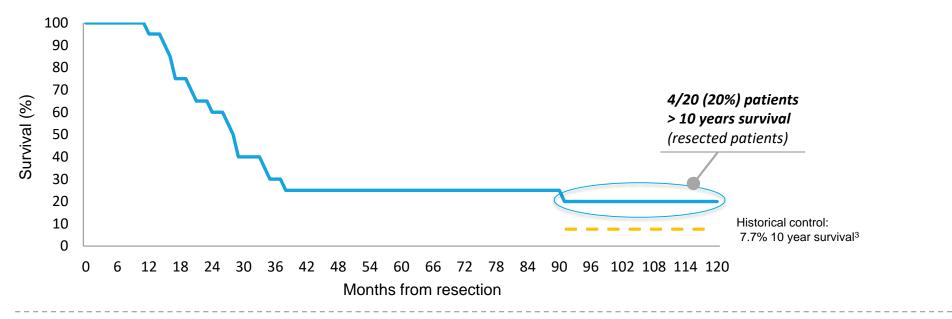






## These results are backed by encouraging 10 year survival data and immune response correlation from earlier trials

#### **Long-term data from earlier TG mono-therapy trials – resected pancreatic cancer**



Advanced pancreatic cancer TG01/GM-CSF (mono-therapy)	Evaluable patients	Median survival (from 1st vaccination)	1 year survival (from 1 <sup>st</sup> vaccination)
Detected immune response	14 / 25 (56%)	156 days	3 (21%)
Not detected Immune response	11 / 25 (44%)	109 days	1 ( 9%)

(Clinical study report CTN RAS 98010 on file)

Significantly better outcome for patients with immune response (non-resected)

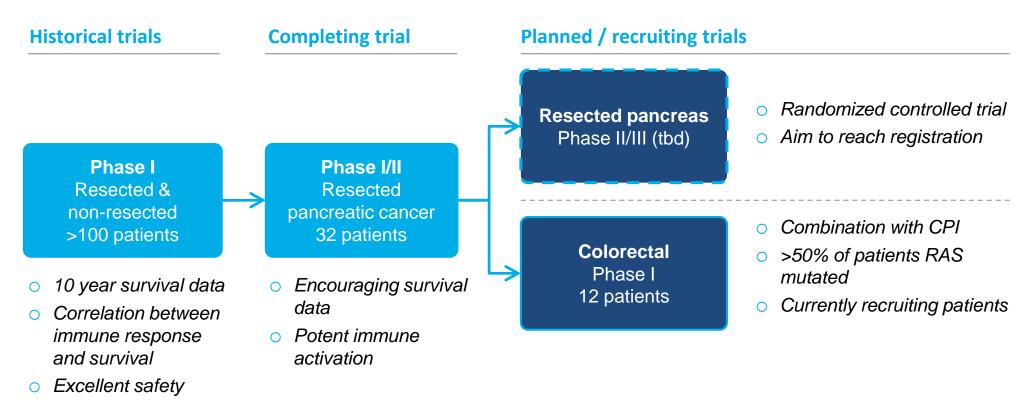


<sup>2</sup> Oettle H et al., JAMA 2007, vol 297, no 3

<sup>3</sup> Oettle H et al., JAMA 2013, vol 310, no 14

<sup>1</sup> Wedén et al., 2011

### We are currently working to replicate and expand on these encouraging clinical results



A randomized Phase II/III registration trial being designed



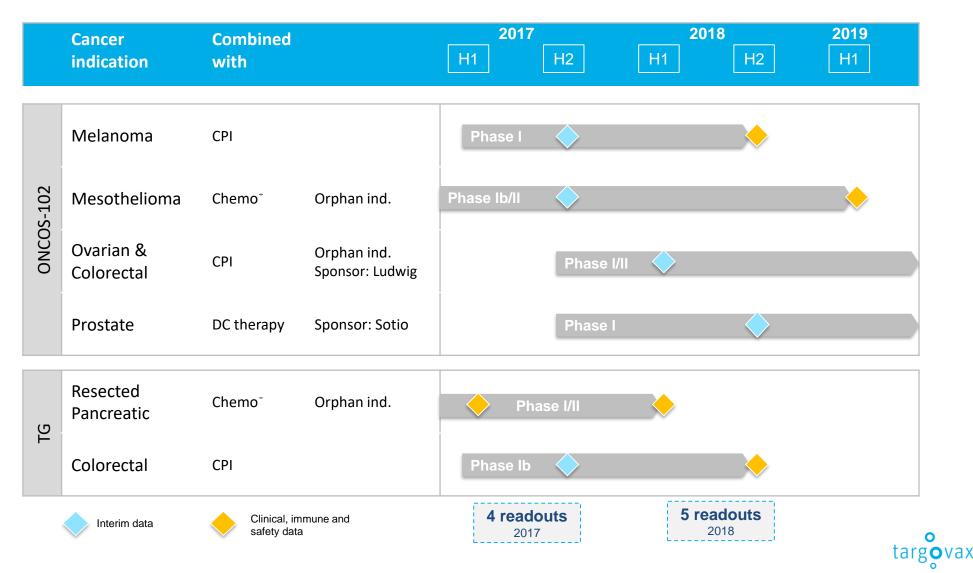
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# Adjuvant therapy for resectable pancreatic cancer

London, June 2017



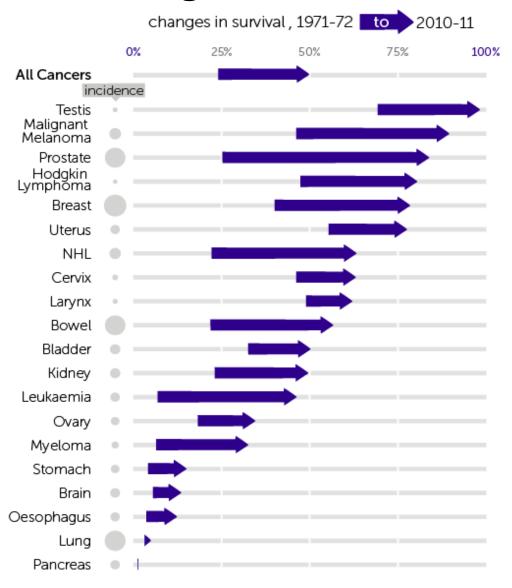
### **Daniel Palmer**

Department of Molecular and Clinical Cancer Medicine
University of Liverpool and Clatterbridge Cancer
Centre

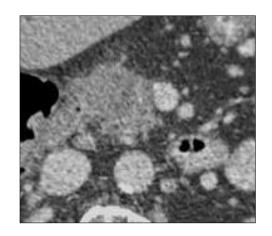
## Plan of the Talk

- Epidemiology
- The challenges of pancreatic cancer
- Palliative chemotherapy: current status
  - Gemcitabine
  - Folfirinox
  - Nab-paclitaxel
- Adjuvant therapies for resected pancreatic cancer
  - Clinical trials
  - Current state-of-the-art
- Where next?
  - Rationale for immunotherapy
- Targovax trial

## Age-Standardised Ten-Year Net Survival Trends, Adults England and Wales, 1971-2011



### Why so challenging?



Resectable 10-20%



Locally advanced 30-40%



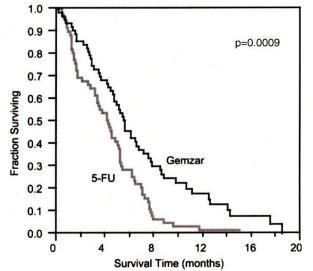
Metastatic 50-60%

- Advanced stage at time of diagnosis
- Even in operable cases
  - Challenging (and dangerous) surgery
  - High recurrence rates
- Relatively resistant to chemotherapy
  - Gemcitabine standard chemotherapy for 20 years
  - Gem vs weekly bolus 5-FU

### Advanced pancreatic cancer is relatively resistant to chemotherapy

Io. at Risk

0



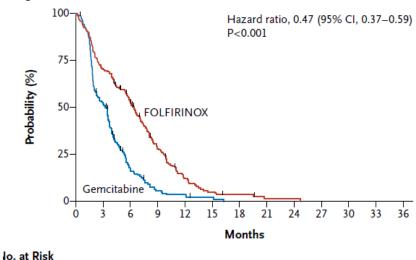
	5-FU	Gem	
Response	0%	5%	
Median OS	4.4m	5.7m	P=0.025
1yr survival	2%	18%	
CBR	4.8%	23.8%	P=0.022

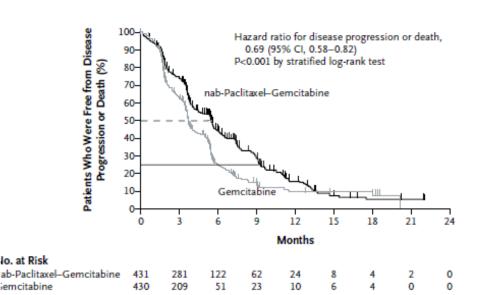
Frogression-iree ourvival

Semcitabine 171

OLFIRINOX 171 121

88 26

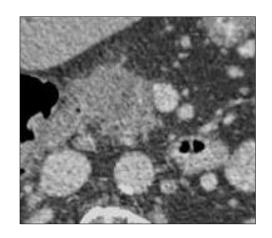




**FOLFIRINOX** 

**GEM+ABRAXANE** 

# Why so challenging?



Resectable 10-20%



Locally advanced 30-40%



Metastatic 50-60%

- Even in operable cases
  - Challenging (and dangerous) surgery
  - High recurrence rates
- Long-term survival <10%</p>
- Is the problem due to:
  - Local recurrence?
  - Metastatic recurrence?
  - Both?

# **Adjuvant Therapy**

The NEW ENGLAND JOURNAL of MEDICINE

#### ORIGINAL ARTICLE

# A Randomized Trial of Chemoradiotherapy and Chemotherapy after Resection of Pancreatic Cancer

John P. Neoptolemos, M.D., Deborah D. Stocken, M.Sc., Helmut Friess, M.D., Claudio Bassi, M.D., Janet A. Dunn, M.Sc., Helen Hickey, B.Sc., Hans Beger, M.D., Laureano Fernandez-Cruz, M.D., Christos Dervenis, M.D., François Lacaine, M.D., Massimo Falconi, M.D., Paolo Pederzoli, M.D., Akos Pap, M.D., David Spooner, M.D., David J. Kerr, M.D., and Markus W. Büchler, M.D., for the European Study Group for Pancreatic Cancer

NEJM 2004; 350:1200-10



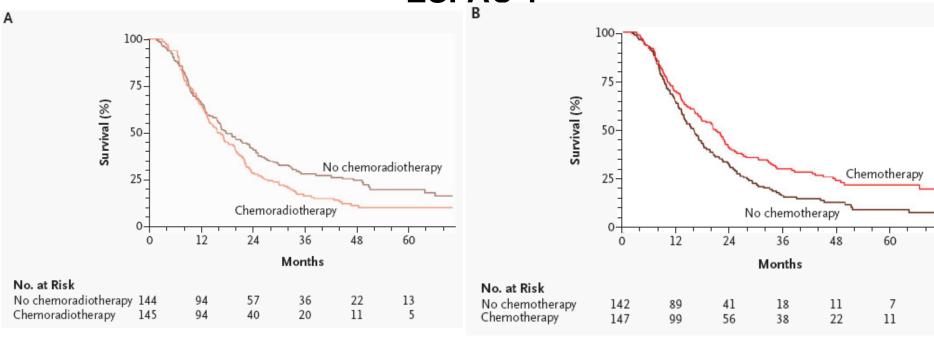






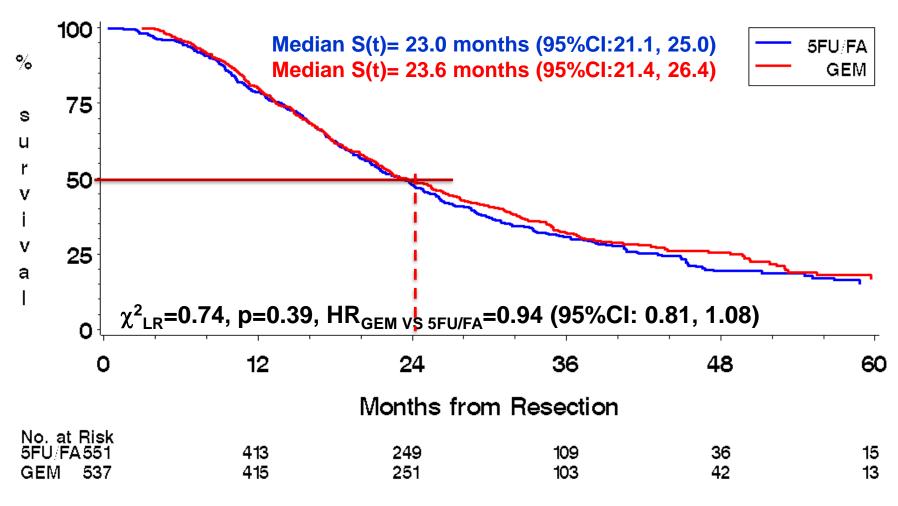


A randomized trial of chemoradiotherapy and chemotherapy after resection of pancreatic cancer – ESPAC 1



NEJM 2004; 350:1200-10

# **ESPAC-3: Survival by treatment**



Neoptolemos et al JAMA 2010; 304: 1073-81















#### 722 patients

pancreatic ductal adenocarcinoma 'curative' resection <12 wks



RANDOMISATION at Liverpool Cancer Trials Unit

#### **GEMCITABINE**

1000mg/m<sup>2</sup>-Days 1,8 and 15 for 6 cycles

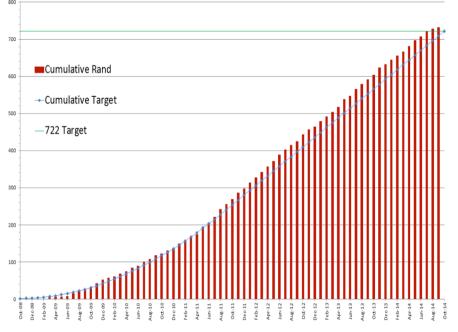
#### **GEMCITABINE**

1000mg/m<sup>2</sup>-Days 1,8 and 15 for 6 cycles CAPECITABINE 1660mg/m<sup>2</sup>/day – 21/28d

i.e. 24 weeks

3-MONTHLY FOLLOW UP FROM RANDOMISATION TO DEATH Stratified log-rank test with 5% 2-sided α, for a 10% difference in 2 year survival, 90% power = 480 events = 722 patients, 361 in @ arm

Target number of patients	722
Start date	13/01/08
Number of sites opened	106
Planned close date	01/11/14
Target achieved	31/07/14

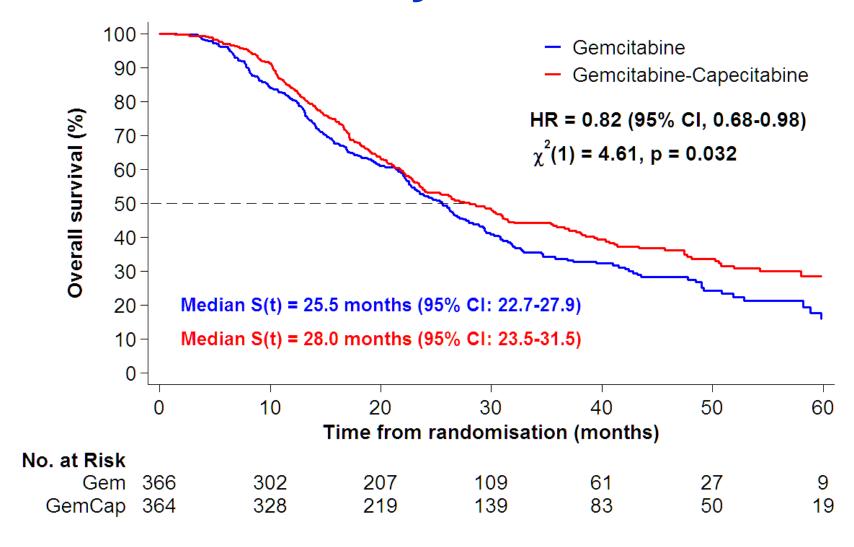


# **Patient Demographics**

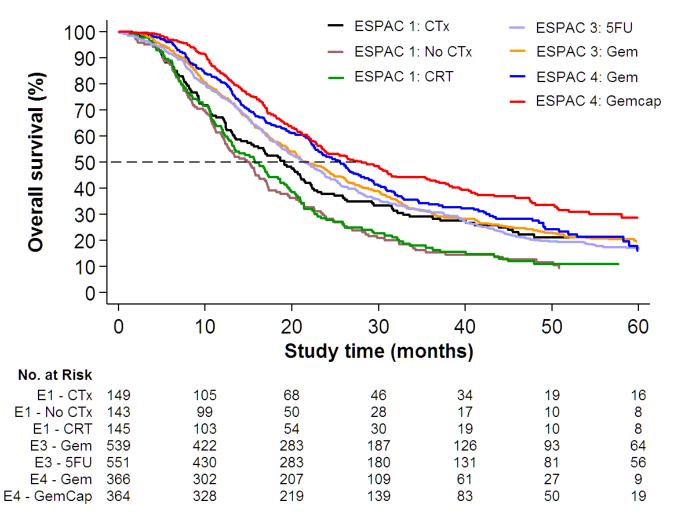
		GEM n=366	GEMCAP n=364	TOTAL n=730
*Age (years)		65 (37-80)	65 (39-81)	65 (37-81)
Sex	Male	212 (58%)	202 (55%)	414 (57%)
	Female	154 (42%)	162 (45%)	316 (43%)
Baseline PS	0	158 (43%)	150 (41%)	308 (42%)
	1	199 (54%)	202 (56%)	401 (55%)
	2	9 (3%)	12 (3%)	21 (3%)
Smoking	Never	151 (41%)	146 (40%)	297 (41%)
	Past	136 (37%)	148 (41%)	284 (39%)
	Present	62 (17%)	61 (17%)	123 (17%)
	Unknown	17 (5%)	9 (2%)	26 (3%)
*Surgery to I	Rand (days)	65 (23-111)	64 (21-111)	64 (21-111)

<sup>\*</sup> Median (Range)

# **Survival by Treatment**



# **ESPAC Trials Overall Survival**



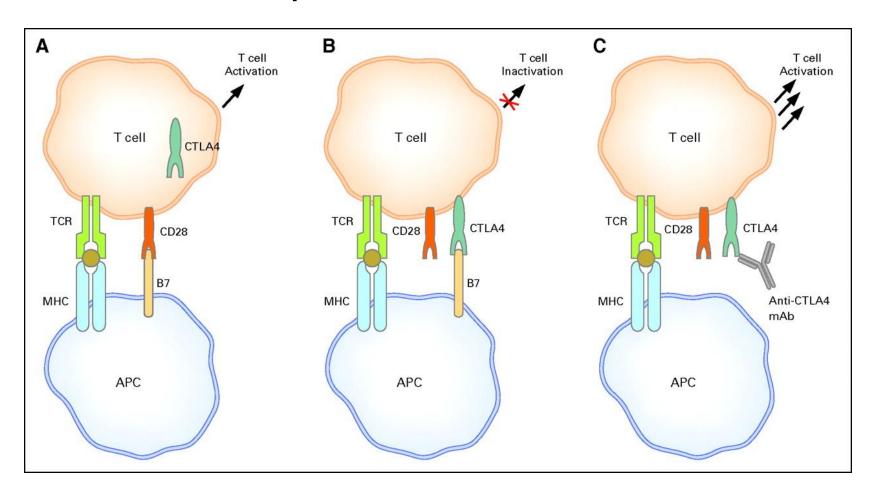
<sup>\*</sup>Study time = time from surgery for ESPAC 1/3, study time = time from randomisation for ESPAC 4

# Where next?

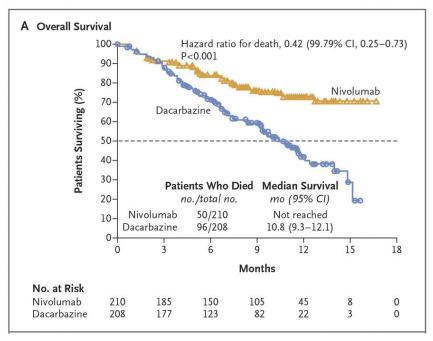
- Rationale for immunotherapy in cancer
- Targovax trial

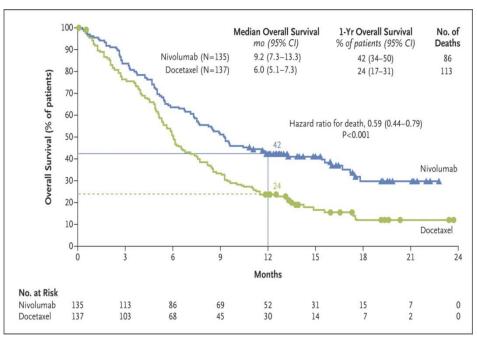
# Immunotherapy approaches

# • T cell checkpoints



# Checkpoint inhibition in advanced melanoma and lung cancer



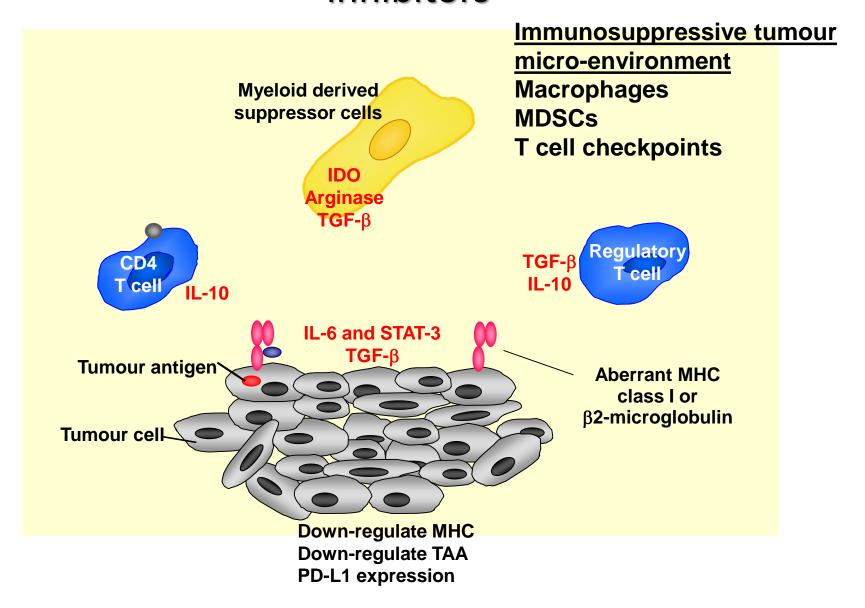


melanoma

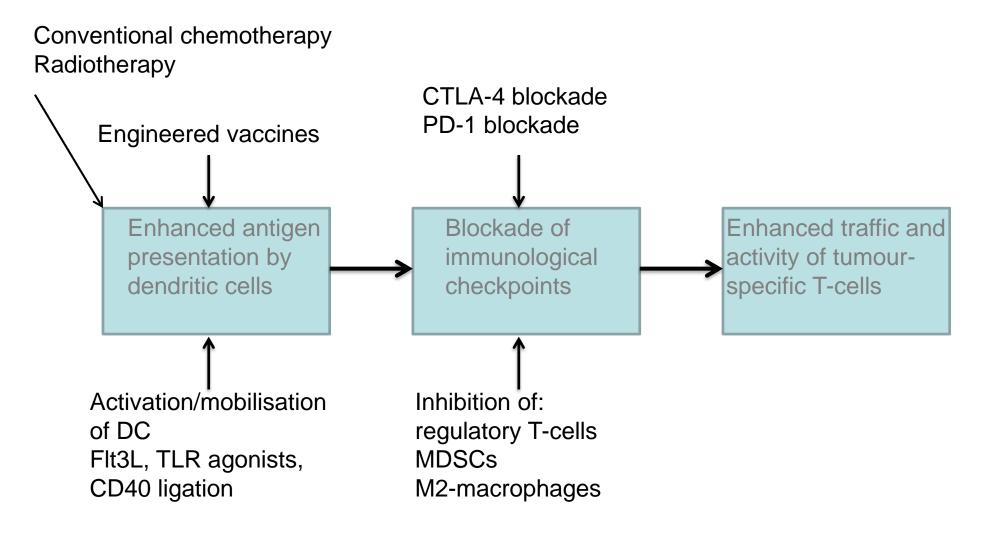
Non-small cell lung cancer

- Significant survival benefit
- Some long-term survivors
- Non-specific immune stimulation
  - Risk of auto-immune toxicities

# Advanced pancreatic cancer is resistant to checkpoint inhibitors



# Multiple points of intervention for immunotherapy







### Arming the immune system to fight cancer

A Phase I/II trial of TG01/GM-CSF and gemcitabine as adjuvant therapy for treating patients with resected RAS-mutant adenocarcinoma of the pancreas

### TG01-01 Background

**TG01** 

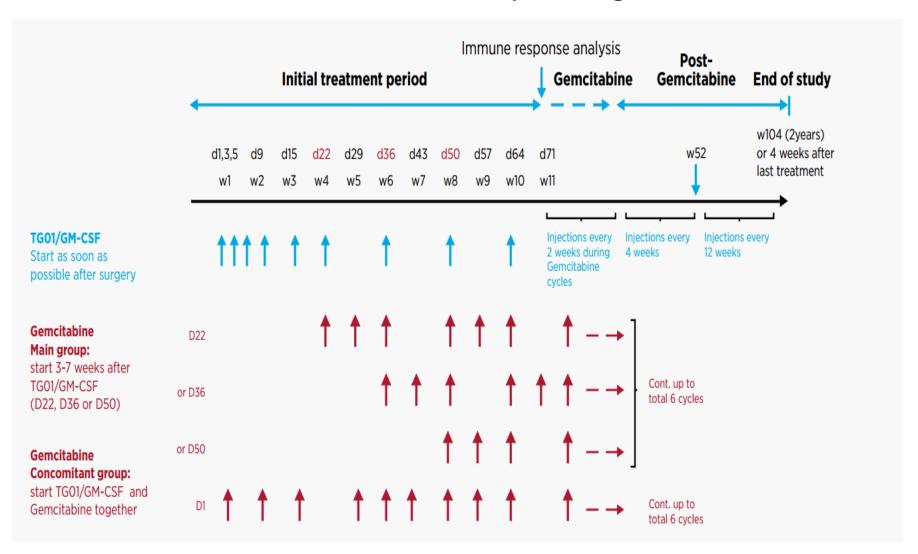
- injectable antigen-specific cancer immunotherapy
- targeted to treat patients with RAS mutation
  - found in more than 85% of pancreatic adenocarcinomas
- a mixture of 7 synthetic peptides
  - representing 7 of the most common 12 & 13 mutations in RAS assoc. with human cancer
- induces RAS mutant-specific T-cell responses which are enhanced by co-administration of GM-CSF

Earlier studies

 demonstrated that adjuvant vaccination with TG01/GM-CSF given as monotherapy to pancreatic cancer patients after tumor resection induce mutant RAS specific immune response in 100% of patients

This study evaluates safety, immunological response and Overall Survival of TG01-immunotherapy with adjuvant gemcitabine chemotherapy.

# TG01-01 Study design



# TG01-01 Study objectives

### **Primary**

- •To assess the safety of GM-CSF/TG01 vaccination and adjuvant chemotherapy
- •To assess the immune response to GM-CSF/TG01 and the effect of adjuvant chemotherapy in patients receiving GM-CSF/TG01 after primary resection of pancreatic adenocarcinoma

### Secondary

•To assess, at 2 years, the clinical efficacy of GM-CSF/TG01 in patients with resected pancreatic cancer

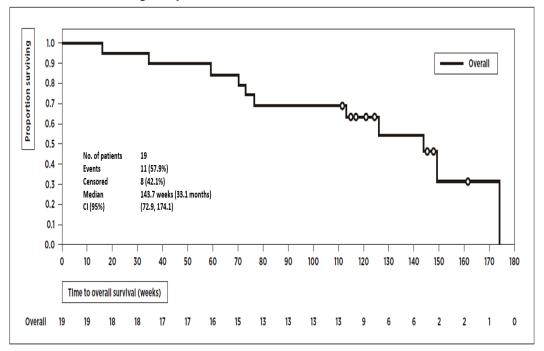
#### **Exploratory**

- •To assess the relationship of KRAS status to recurrence
- To monitor CA19-9 levels

# Demographics

Parameters	Number of patients (N=19)
Age (Y) median (min, max)	67 (49, 79)
Gender, n (%)	
Male	10 (53%)
Female	9 (47%)
ECOG, n (%)	
0	8 (42%)
1	11 (58%)
CA19-9 (n=15) U/ml median (min, max)	16 (8, 240)
Hemoglobin (g/L) median (min, max)	124.0 (104, 153)
Disease staging at diagnosis	
T stage	
T1	1 (5%)
T2	1 (5%)
T3	17 (90%)
N stage	
NO NO	7 (37%)
N1	12 (63%)
M stage	
MO	19 (100%)
Resection surgical outcome, n (%)*	
RO	6 (32%)
R1	13 (68%)
KRAS mutation detected, n (%)	
Yes	16 (84%)
No	3 (16%)
Time from surgery to first IMP adm (week) median (range)	8 (7-12)

# TG01-01 Efficacy (survival rate from resection)



	1 year*	2 years*
Assessed from resection (8 weeks before first IMP)	17/19 (90%)	13/19 (68%)

Compares favorably with published historical two-year survival rates of resected cancer patients treated with gemcitabine alone of 30%-53%<sup>1-5</sup>

## TG01-01 Immune response

### Immune response by week 11 and entire study period (N=19)

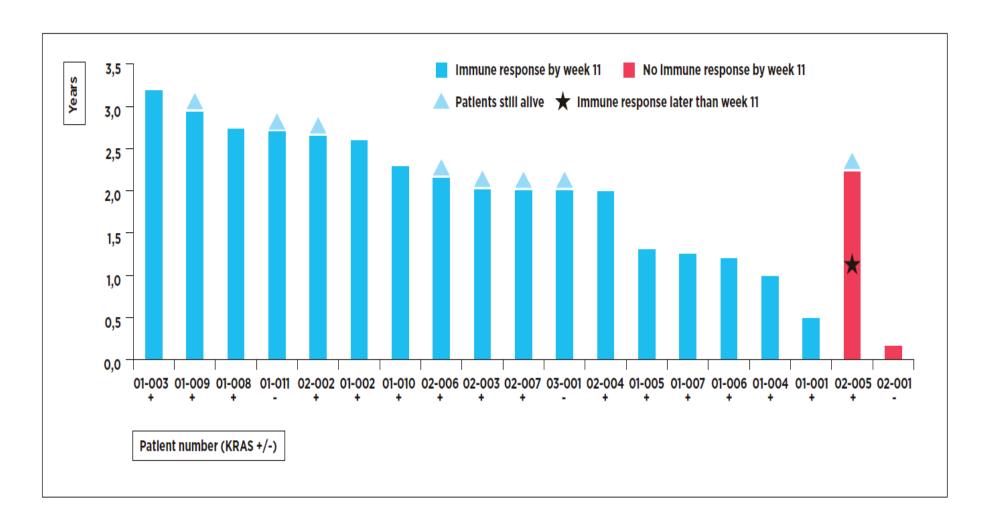
Study period	Immune responders	Immune responders DTH	Immune responders T-cells
By end of initial treatment (week 11)	17/19 (89%)	16/19 (84%)	10/19* (53%)
Entire study period	18/19 (95%)	18/19 (95%)	14/19* (74%)

<sup>\*</sup>Three patients (week 11) and two patients (entire study period) without blood samples for analysis

### Immune response after week 11 (n=11)

Study time point	No. of pts with immune monitoring after week 11	Patients with positive immune response after week 11
After week 11	11	9/11 (82%)

### TG01-01 Overall survival and immune response



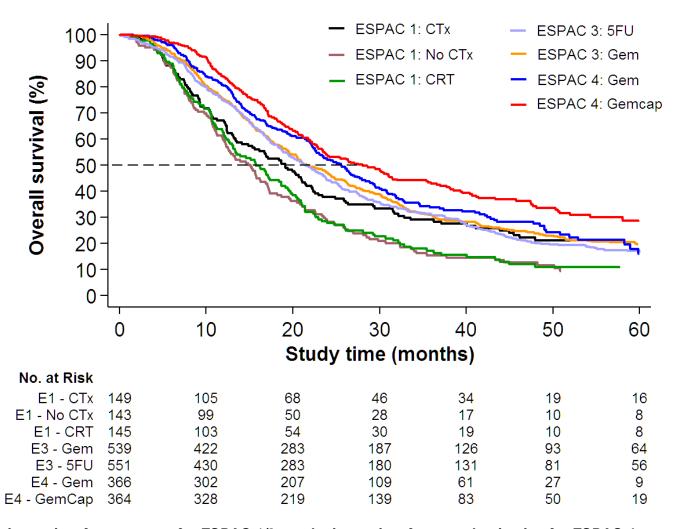
# TG01-01 Safety profile (N=19)

Serious Adverse Events Preferred term	Number of Events	Relationship to study treatment	
Anaphylactic reaction	2	Deleted to TCO1 / CM CC	
Hypersensitivity	1	Related to TG01 +/- GM-CSF	
Dyspnea	1	Related to Gemcitabine and TG01/GM-CSF	
Lung infection	1		
Pyrexia (fever)	2	Related to Gemcitabine	
Anaemia	1		
Anaphylactic shock related to a concomitant medication (Emend)	1		
Hyperglycemia	1		
Urosepsis	1	Unrelated to study treatments	
Pneumonia	1		
Viral upper respiratory tract infection	1		

### **TG01-01 Conclusions**

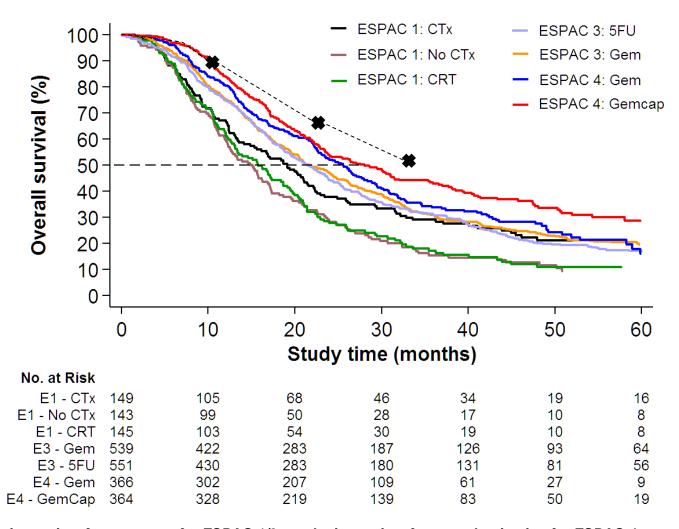
- TG01/GM-CSF generated early immune responses in 89% of patients with R0/R1 resected pancreatic cancer. This demonstrate that TG01 vaccination activate mutant RAS specific T cells.
- The regimen was generally well tolerated although some late, manageable allergic reactions were seen.
- Median OS of 33.1 months is encouraging in context of published data
- Immune activation at both DTH and PBMC level is associated with the positive clinical findings.

### **ESPAC Trials Overall Survival**



<sup>\*</sup>Study time = time from surgery for ESPAC 1/3, study time = time from randomisation for ESPAC 4

### **ESPAC Trials Overall Survival**



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## **Capital Markets Update - Agenda**

- Introduction CEO, Øystein Soug
- Targovax's technology and trials CMO, Dr Magnus Jäderberg
- A physician's view on pancreatic cancer *Prof Daniel Palmer*
- Financial update CFO, Erik Wiklund
- Q&A



### Financial summary – end of Q1 2017

# Raised NOK 200 million 8 June 2017 10,000,000 new shares @ NOK 20 per share

**Operations** Cash **NOK 147m** USD 17m End of Q1 2017 Net cash flow NOK -24m USD -3m Total Q1 Annual run rate **NOK 104m** USD 12m *Last four quarters* Annual opex **NOK 116m** USD 13m *Last four quarters* 

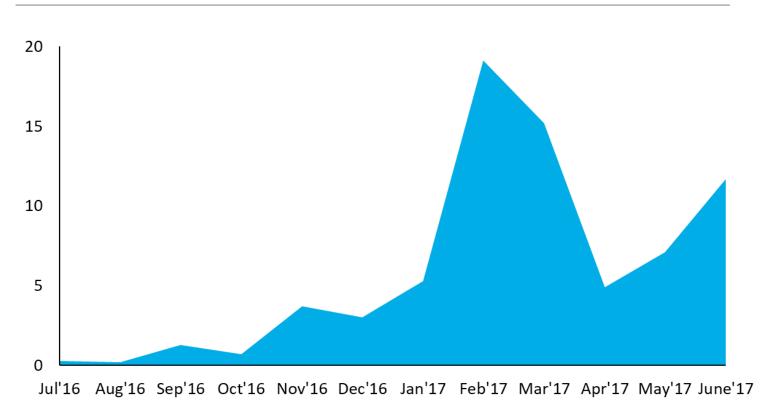
The share	OSE: TRVX		
Market Cap	NOK ~1bn	USD ~120m	At share price NOK ~24
Daily turnover	NOK 10m	USD 1m	Typical daily volume
Debt	NOK 43m	USD 5m	EUR 6m conditional
No. of shares	42.2m		46.0m fully diluted per April 18
Analysts DNB, ABG Sundal Collier, Arctic, Redeye, Norske Aksjeanalyser			



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# TRVX was upgraded to the main list on OSE in March, and has showed a positive trend in share turnover in 2017

#### Development in daily average share turnover (NOK million / day)\*



- NOK ~1b market cap
- NOK 10m NOK avg. daily turnover in last 3 months
- NOK 850m total turnover in Q1
- 560k shares avg. daily volume in Q1
- >3,700 owners
- 42.2m shares\* (46.0 fully diluted)



<sup>\*</sup> Up until 8th June

<sup>\*</sup> Before Private Placement 8th June

### Strong shareholder base as per May 2017

Shareholder		Estimated ownership	
		Shares m	Relative
HealthCap	Sweden	11,2	26,4 %
RadForsk	Norway	4,1	9,7 %
Nordea	Norway	3,0	7,0 %
Nordnet Livsforsikring	Norway	1,5	3,5 %
KLP	Norway	1,3	3,1 %
Statoil	Norway	0,9	2,2 %
Danske Bank (nom.)	Norway	0,8	1,9 %
Timmuno AS	Norway	0,7	1,7 %
Prieta AS	Norway	0,7	1,7 %
Nordnet Bank AB (nom.)	Sweden	0,7	1,6 %
Thorendahl Invest AS	Norway	0,3	0,7 %
Sundt AS	Norway	0,3	0,7 %
Netfonds Livsforsikring AS	Norway	0,3	0,6 %
Avanza Bank AB (nom.)	Sweden	0,3	0,6 %
The Bank of NY Mellon (non	n. Belgium	0,2	0,5 %
Tobech Invest AS	Norway	0,2	0,5 %
Istvan Molnar	Norway	0,2	0,4 %
Danske Bank (nom.)	Norway	0,2	0,4 %
NHO - P665AK	Norway	0,2	0,4 %
Kristian Falnes AS	Norway	0,2	0,4 %
Top 20		27,0	64,1 %
Other shareholders (3772)		15,2	35,9 %
Total		42,2	100,0 %

#### **New shareholders in Private Placement:**

- Nyenburgh
- Trium
- Millenium Capital Partners
- Interogo
- AP3
- Aramea AM

#### 42.2m ordinary shares<sup>1</sup>

- Management ownership: 2.1%
- 3,792 shareholders

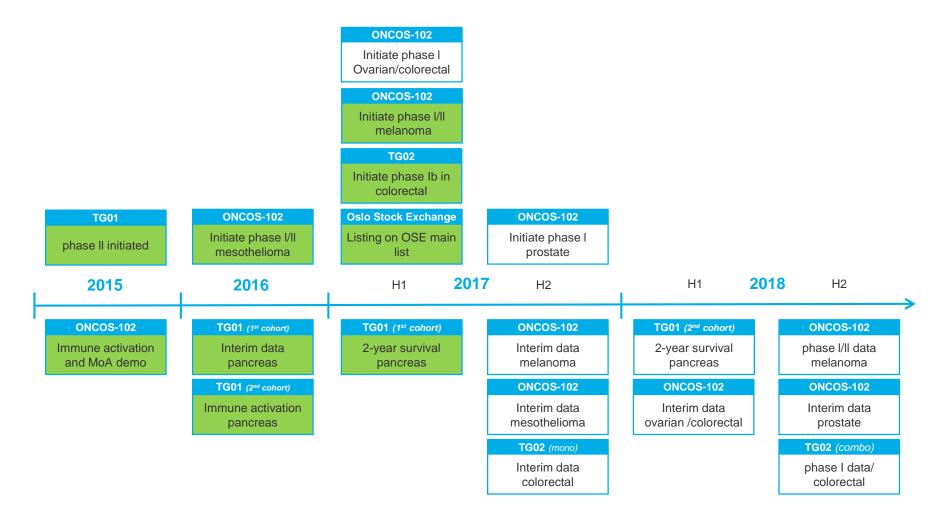
#### 46.0m<sup>2</sup> shares fully diluted\*

- Average strike price on options ~NOK 21
- Total dilutive effect of options is 7.9%

argovax

 $<sup>^{</sup>m 1}$  Includes outstanding options (3,634,263) and Restricted Stock Units (169,128) to Board members

### Multiple near term value inflection points





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