



# **Faron Pharmaceuticals (LSE: FARN)**

*Full year 2018 results*

*Annual General Meeting 28 MAY 2019*

*CEO Markku Jalkanen*

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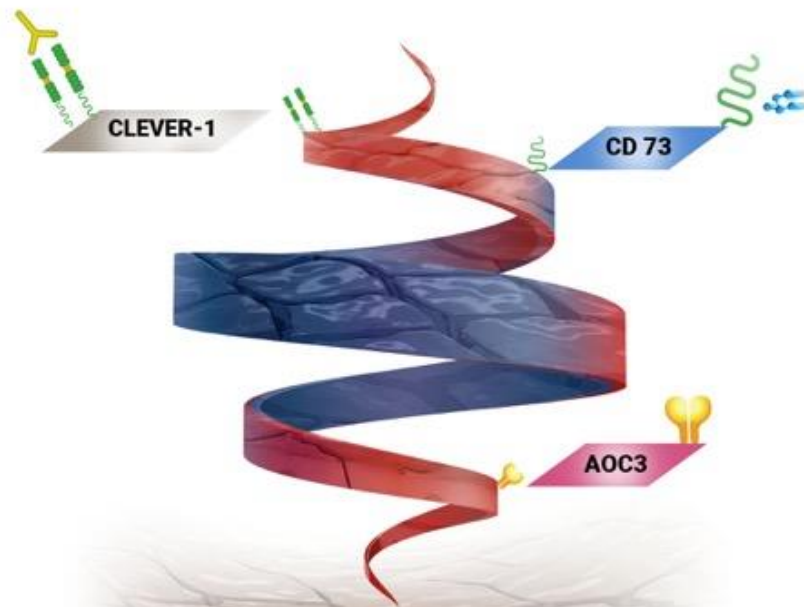
## WE SEE BARRIERS AS OPPORTUNITIES

Faron's pipeline is based on receptors involved in regulation of immune responses and vascular dysfunctions

### Immuno-Oncology

Clevegen®

Cleaver-1 regulates tissue immune status



### ARDS & Organ protection

Traumakine®

CD73 controls capillary leakage and escalation of inflammation

AOC3 escalates inflammation and vascular damage\*

\*AOC3 inhibitor currently on hold

The endothelial surface of exhaustive capillary networks (100,000 km/individual) controls fluid and cell balance between circulation and tissues, and is a factor in many devastating diseases such as organ failures and cancer metastasis

# FARON PIPELINE

## Traumakine®

Enhancing the endothelial barrier function against ischaemic conditions



Program	Program indication	Research	Preclinical development	Phase I/II	Phase III	MAA/BLA	LAUNCH	Partnered
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### Acute Respiratory Distress Syndrome (ARDS)



FP-1201-Iyo Interferon β	CD 73 ARDS EU	[Progress bar]						
FP-1201-Iyo Interferon β	CD 73 ARDS Japan	[Progress bar]						
FP-1201-Iyo Interferon β	CD 73 CALIBER Global	[Progress bar]						

\* Subject to regulatory discussions and approvals and partnering discussions

### Multi Organ Failure (MOF)



FP-1201-Iyo Interferon β	CD 73 RAAA	[Progress bar]						
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### Single organ injury

FP-1201-Iyo Interferon β	CD 73 n/a	[Progress bar]						
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### D-ARDS



FP-1201-Iyo Interferon β	CD 73 INTEREST	[Progress bar]						
FP-1201-Iyo Interferon β	IFN-beta receptor SNP Global	[Progress bar]						

\* Subject to regulatory discussions and approvals and partnering discussions

## Clevegen®

Switches immune suppressive M2 macrophages to immune stimulating M1 macrophages



Program	Program indication	Research	Preclinical development	Phase I/II	Phase III	MAA/BLA	LAUNCH	Partnered
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### Immuno-oncology



FP-1305 Antibody	Clever-1 Hepatobiliary cancers	[Progress bar]						
FP-1305 Antibody	Clever-1 Pancreatic cancer	[Progress bar]						
FP-1305 Antibody	Clever-1 Ovarian cancer	[Progress bar]						
FP-1305 Antibody	Clever-1 Colorectal cancer	[Progress bar]						
FP-1305 Antibody	Clever-1 Metastatic melanoma	[Progress bar]						
FP-1305 Antibody	Clever-1 Glioblastoma	[Progress bar]						
FP-1305 Antibody	Clever-1 Anti-CD20 resistant lymphomas	[Progress bar]						
FP-1305 Antibody	Clever-1 TAM-positive Hodgkin's lymphomas	[Progress bar]						

## KEY PIPELINE HIGHLIGHTS

### Traumakine

- Corticosteroid interference identified both in European and Japanese phase III studies
- Japanese results inline with INTEREST study
- Corticosteroid resistant polymorphism identified with good Traumakine efficacy
- Advanced interim read out for INFORAAA expected in Q2 2019
- YODA recruitment completed and results expected in Q2 2019

### Clevegen

- No signs of toxicity in pre-clinical studies or human dosing up to date
- Clevegen manufacturing and packaging completed
- MATINS phase I/II initiated in five different solid tumours (colorectal, pancreas, liver, ovarian and melanoma)
- Active immune switch observed in study subjects and first partial responder reported
- Colorectal cancer selected as a first expansion cohort for the MATINS study part II
- *Bexmarilimab* – an INN name for Clevegen proposed by WHO

## KEY FINANCIAL & CORPORATE HIGHLIGHTS

(including Post Period-end)

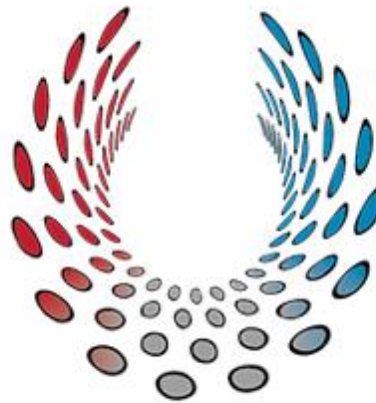
### Financial

- ❑ Raised £15m in February 2018
- ❑ Extensive cash saving program applied post negative INTEREST study results
- ❑ Cash balance of €4.1m on 31 December 2018 and €4.9m on 31 March 2019
- ❑ Operating loss of €20.1m (2017: €21.1m)
- ❑ Net assets of €0.4m on 31 December 2018 and €0.7m on 31 March 2019
- ❑ Raised additional equity (€4,5 million before expenses) in two tranches during March – May 2019

### Corporate

- ❑ Voluntary salary and fee savings by Board and CEO
- ❑ Structural alignment of management team with current objectives
- ❑ A Scientific advisory board was set up with Dr Jonathan Knowles as the chairman
- ❑ Board members Dr Jonathan Knowles and Dr Huaizheng Peng resigned from the board

# INTERFERON-BETA TREATMENT OF ARDS AND OTHER ISCHAEMIC REPERFUSION INJURIES



**TRAUMAKINE**

# ACUTE RESPIRATORY DISTRESS SYNDROME (ARDS)

It's what you die of in influenza, pneumonia, sepsis, and major trauma

**ARDS is an inflammatory lung injury leading to vascular leakage filling the lungs with fluid – “drowning within”**

## The burden of ARDS

- Over 300,000 cases annually in EU & US, and 3 million worldwide<sup>1</sup>
- **Mortality 30–40%**<sup>2</sup>
- At average an ARDS patient spends 25 days in the ICU and 47 days in the hospital<sup>2</sup>
- This accounts to 3.6 million hospital days each year in the USA<sup>3,4</sup>
- 70–100% suffer from cognitive impairment at hospital discharge<sup>5</sup>
- Only 48% are able to return work after 1 year<sup>4</sup>

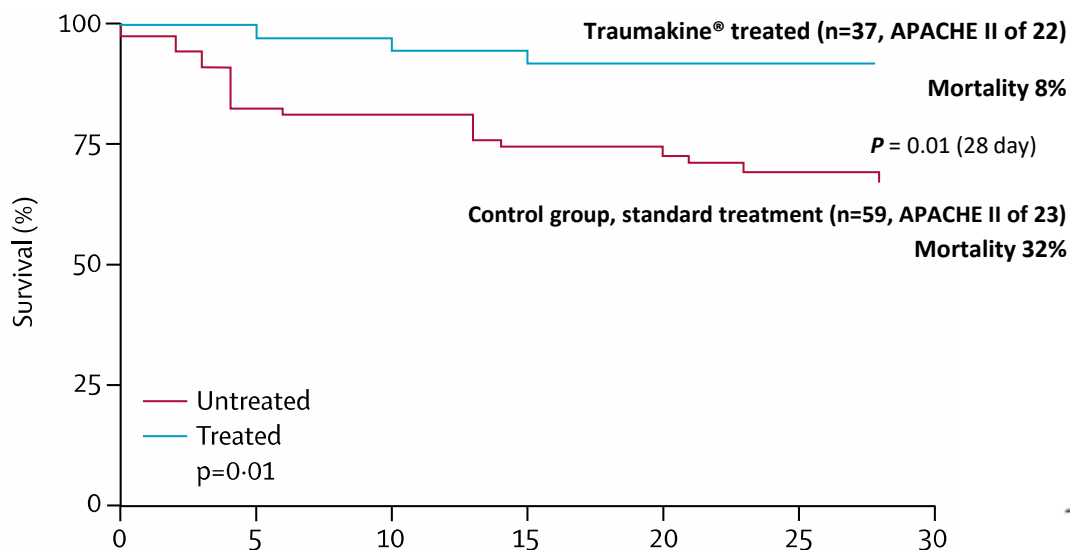




# PHASE I/II PROOF OF CONCEPT TRIAL RESULTS

Reduction in ICU stay from 28 to 16 days, less need for dialysis between groups

## Primary endpoint: significant drop in mortality\*



Phase I/II trial showed a significant reduction in mortality with positive secondary endpoints

THE LANCET Respiratory Medicine

### No safety issues

- Interferon Beta, has good safety profile and in chronic use with MS patients worldwide
- Optimal tolerated dose established
- Short treatment period

### Positive secondary endpoints

- Mortality at six months was lower than expected
- Improvement in lung function and functional assessments aligned with improvement in lung function and general dysfunction
- Efficacy improvements are consistent with a reduction in vascular leakage

\*Of the 37 patients treated with Traumakine®, 32 were diagnosed with ARDS (PaO<sub>2</sub>/FiO<sub>2</sub> ≤200 mmHg) and 5 patients were diagnosed with ALI (PaO<sub>2</sub>/FiO<sub>2</sub> ≤300 mmHg). 30% of the treated patients were diagnosed with sepsis and 41% with pneumonia. The study was carried out in 8 ICU centers in the UK (Bellingan et al. (2014) Lancet Res. Med. 2: 98-106)

# PHASE III INTEREST TRIAL: DESIGN & RESULTS

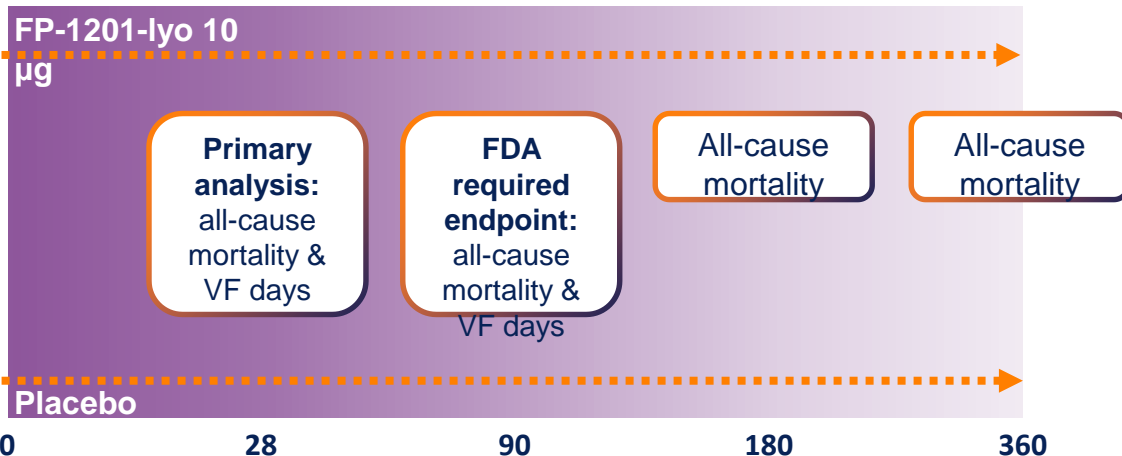
Multi center, double blind, 1:1 randomized, pan-European trial<sup>1,2</sup>

N=301 (296 dosed)

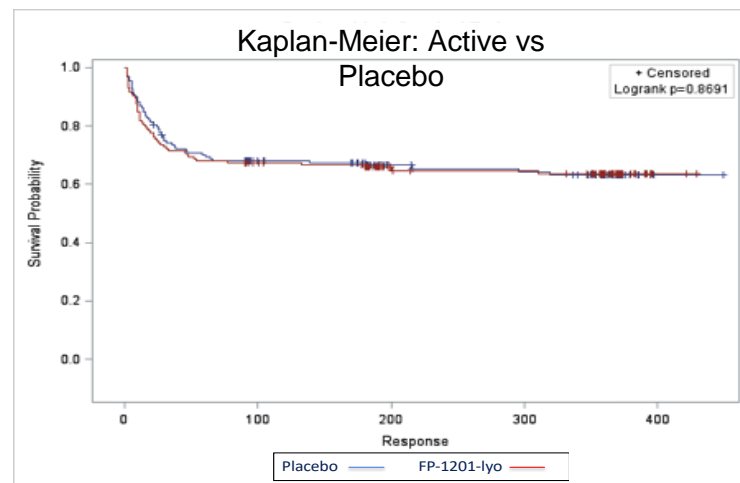
### Eligible patients

- ≥18 years
- Receiving mechanical ventilation
- Moderate or severe ARDS

Dosing regimen  
IV once daily  
for 6 days

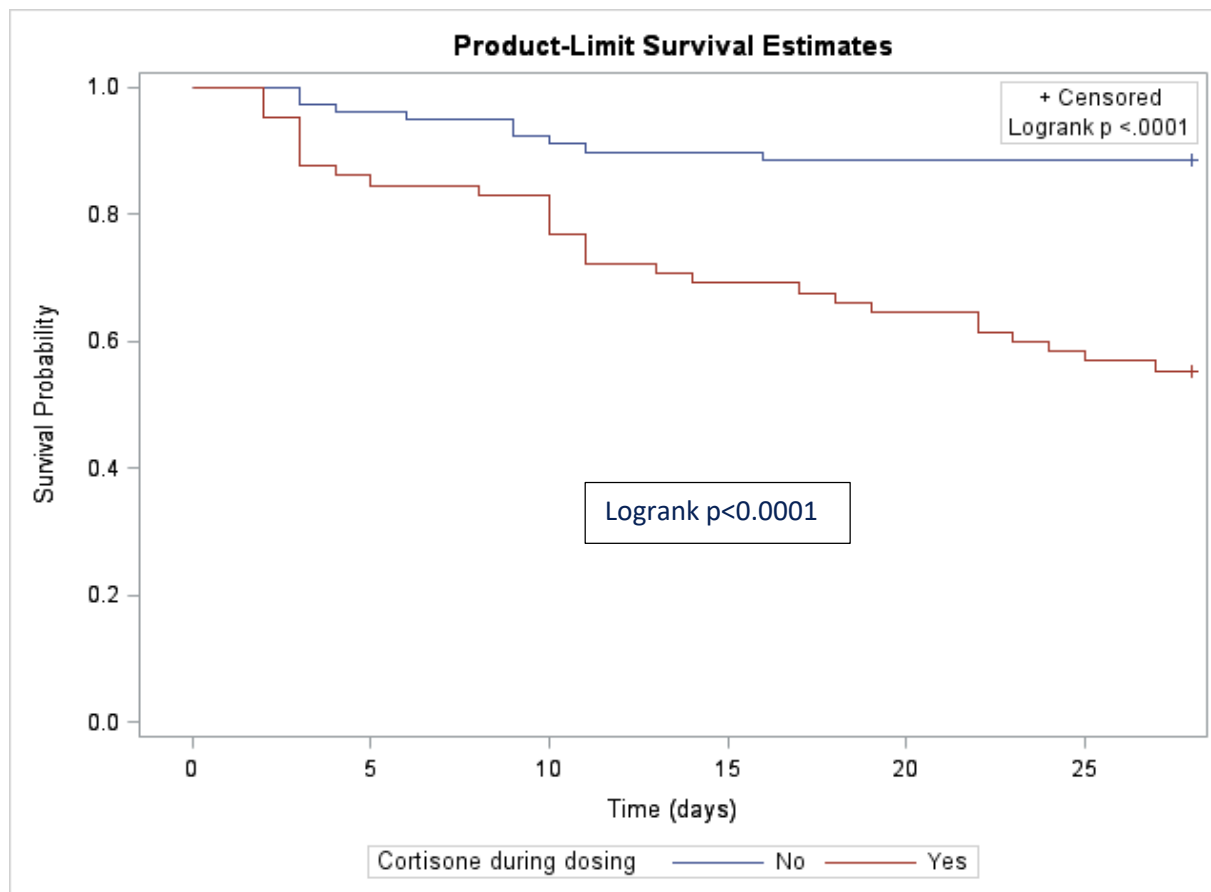


- No difference between groups
- Placebo mortality low due to pneumonia without organ damage
- Post hoc analysis suggests that concomitant steroid use blocks interferon beta activity and increases mortality risk **by 7x**
- Post hoc analysis also suggests that **Traumakine effective without concomitant use of steroids (D28 mortality 10.6%) (see next slide)**



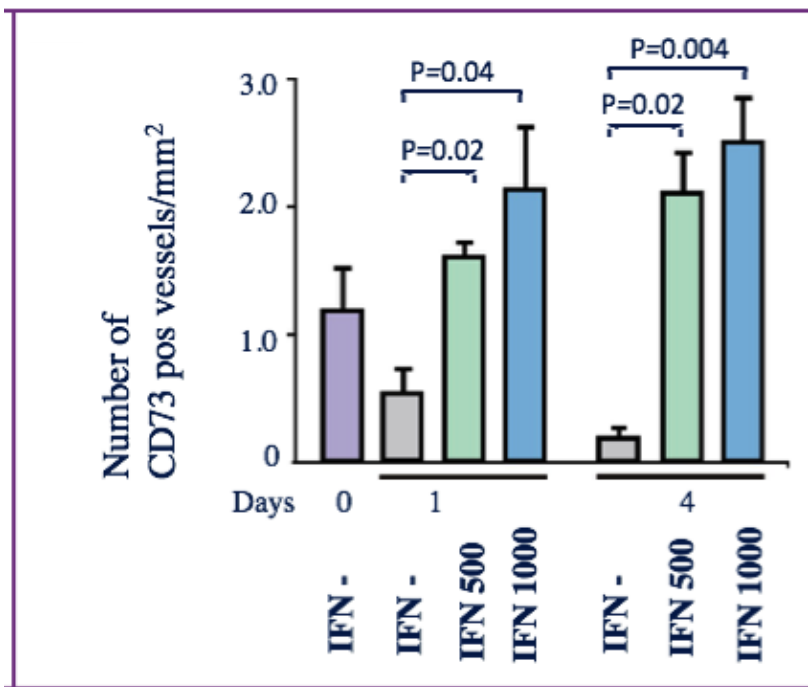
# CONCOMITANT CORTICOSTEROID USE INCREASES MORTALITY

Post hoc analysis of INTEREST trial data base of the active arm

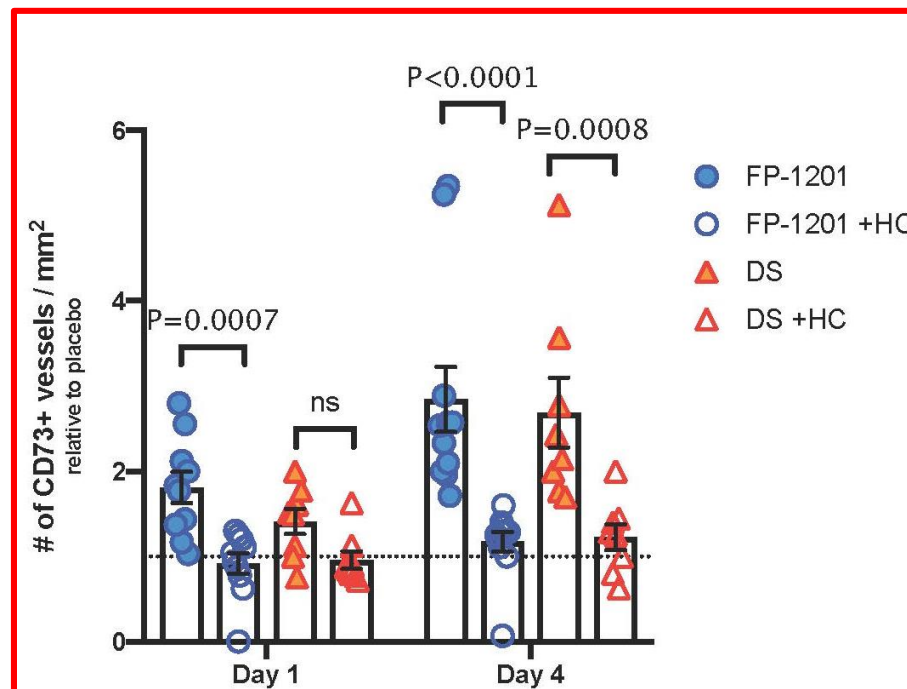


# STEROIDS BLOCK TRAUMAKINE INDUCED CD73 UP-REGULATION

Testing human lung tissue *ex vivo* samples proves steroid interference of Traumakine action



Interferon-beta induced lung capillary CD73 upregulation as published previously in Bellingan et al. 2014. 2:98-107

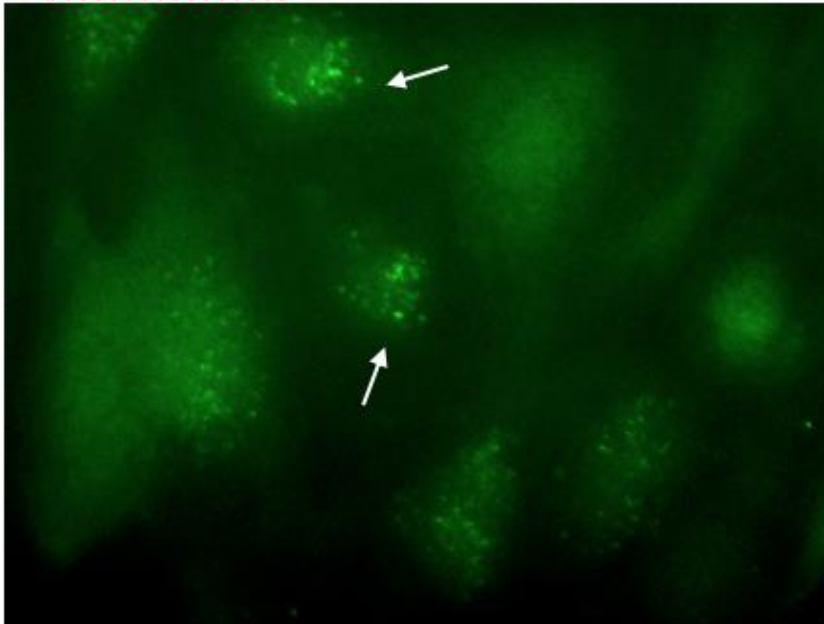


Interferon-beta (DS) induced lung capillary CD73 upregulation is prevented by concomitant steroid (HC). Tests carried out by the same research laboratory (MediCity, Turku University) as in Bellingan et al. 2014. 2:98-107

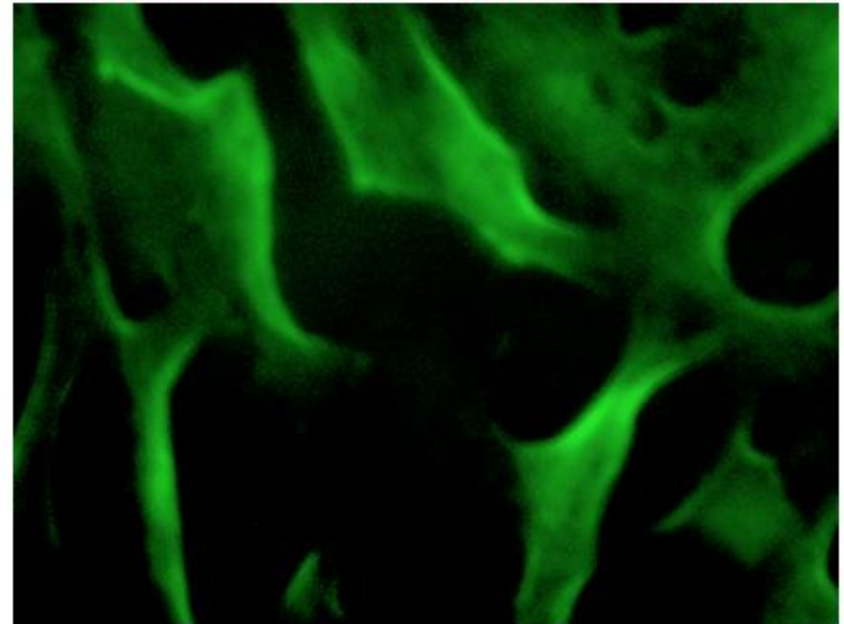
## CORTICOSTEROIDS INHIBIT IFN BETA-1A INDUCED NUCLEAR TRANSLOCATION OF IRF9 IN HUMAN LUNG ENDOTHELIAL CELLS

IRF9 deficiency leads to death in childhood influenza

### A) Treatment: IFN $\beta$



### B) Treatment: IFN $\beta$ + hydrocortisone



Without the overlapping use of hydrocortisone IFN beta-1a activates its nuclear response element by its main transcription factor (IRF9) that moves from the cytoplasm to the nucleus (arrows) to start protein transcription. Among these proteins is CD73. B) Hydrocortisone blocks the translocation of IRF9 into the nucleus, thus preventing CD73 transcription from activating.

## FUTURE TRAUMAKINE STEPS

### Traumakine

- Design of the new phase III study CALIBER based on INTEREST data post hoc analysis
- Seek scientific advise for CALIBER study from regulatory authorities
- Initiate preparations for the global CALIBER study
- CALIBER initiation post external funding
- Continue interactions with key ICU opinion leaders to minimize corticosteroid use in ARDS patients
- Seek publications in leading peer-reviewed journals



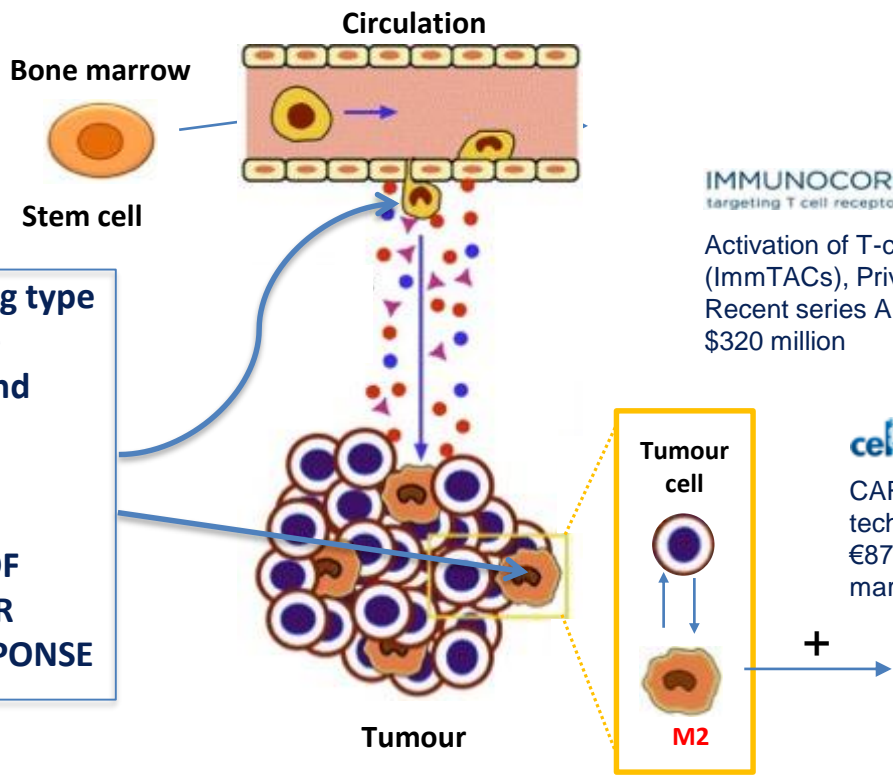
# Turn on your immunity



# CANCER IMMUNOTHERAPY BASED ON TYPE II MACROPHAGE (M2) ELIMINATION

Clevegen limits the function of tumour associated type II macrophages (M2 TAM), a known immunosuppressive cell group in tumours

**Faron: Blocking type II macrophage penetration and function with Clevegen\* → ACTIVATION OF ANTI-TUMOUR IMMUNE RESPONSE**



**IMMUNOCORE**  
targeting T cell receptors  
Activation of T-cells (ImmTACs), Private, est. Recent series A raised \$320 million

**cellectis**  
CAR-T technology, €875 million market cap

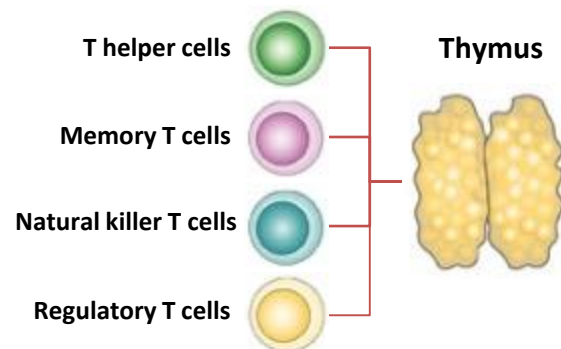
## CURRENT LANDSCAPE



Activation of T-cells (eACT), acquired by Gilead for \$11.9bn (Aug 17)



Activation of T-cells (T-CAR), acquired by Celgene for \$9bn (Jan 18)

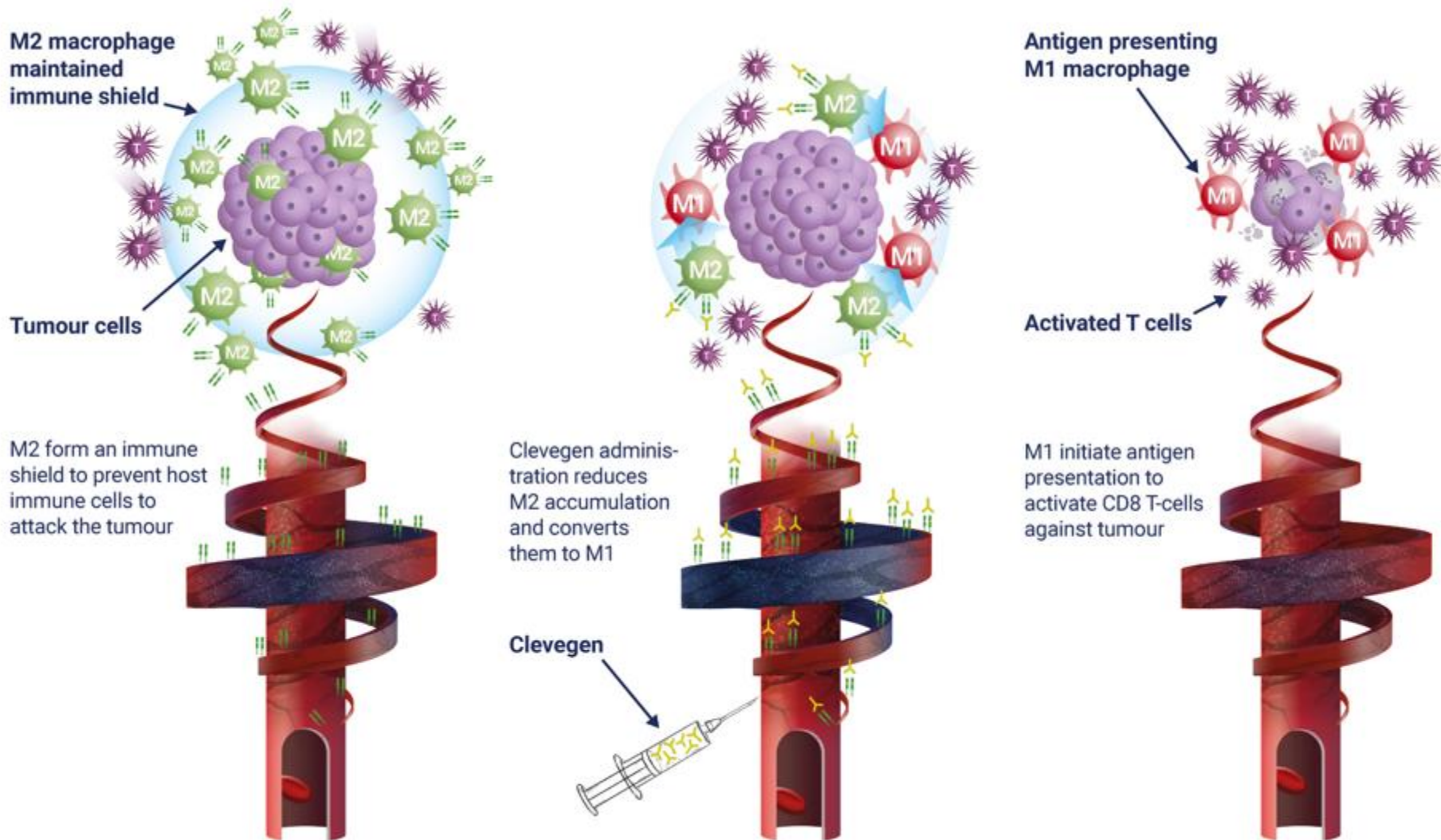


PD-1 inhibitors, sales and sales potential, \$30.0+ billion

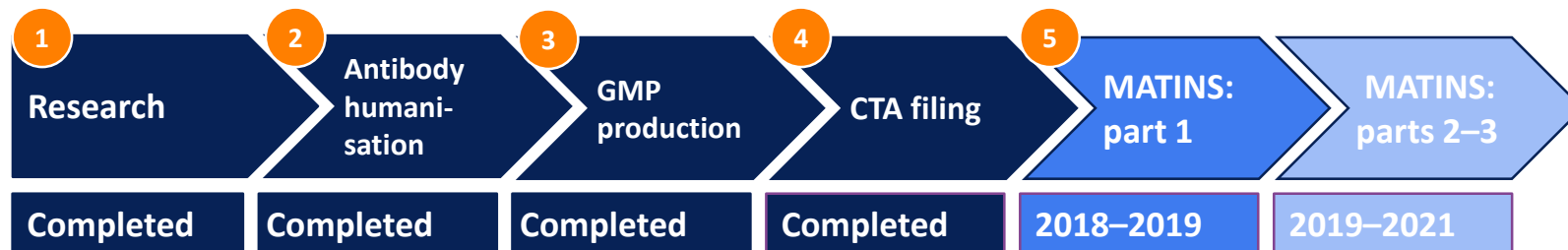
\* Karikoski et al. (2014) Clin. Cancer Res. 20:6452-64; Viitala et al. (2019) Clin. Cancer Res., in press



# CLEVEGEN® MODE OF ACTION IN CANCER FIGHT



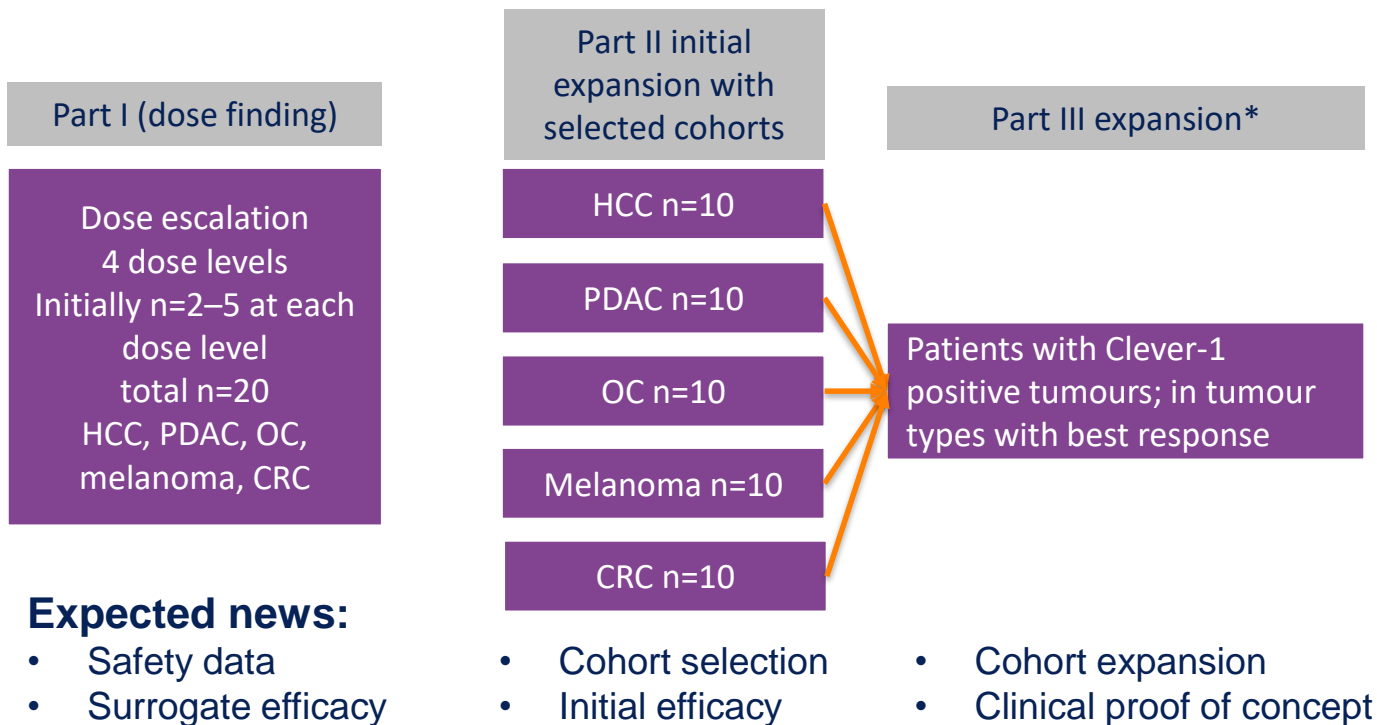
## CLEVEGEN® DEVELOPMENT PATHWAY



- 1 Excellent IP coverage on Clever-1 target and function blocking antibodies
- 2 The product is an anti-Clever-1 antibody (Clevegen®, FP-1305) humanised in collaboration with an antibody technology company Antitope (Cambridge, UK)
- 3 Manufactured by Abzena (San Diego, CA) in high production clones prepared by Selexis (Geneva, Switzerland). *Bexmarilimab* approved by WHO as international nonproprietary (INN) name .
- 4 Primate tox studies completed. MHRA advice in January 2018 for adaptive protocol focusing on safety and early efficacy in four solid tumours (see below) following CTA filings in Finland, UK and Holland
- 5 Phase I/II safety and initial efficacy focused study in HCC (hepatocellular carcinoma) and other solid tumours (pancreatic, ovarian and colorectal cancers as well as metastatic melanoma) started in December 2018. For early observations see upcoming slides.

# MATINS STUDY STRUCTURE

Escalate the dose to tolerated dose & observe biomarkers; learn as you go



**Seeking to build awareness and interest among KOLs and possible commercial partners active in immuno-oncology space**

## PRESENTLY AVAILABLE MEAN SURROGATE MARKER DATA\* FROM MATINS PATIENTS (N=5)

Trial has progressed to 3mg/kg with no serious drug related adverse events observed  
 First patient now dosed also in UK at The Royal Marsden Hospital with similar response

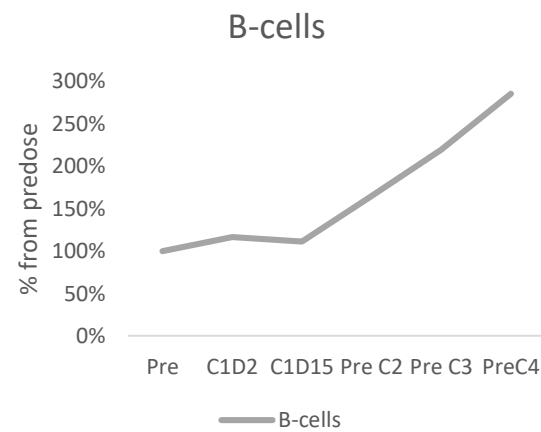
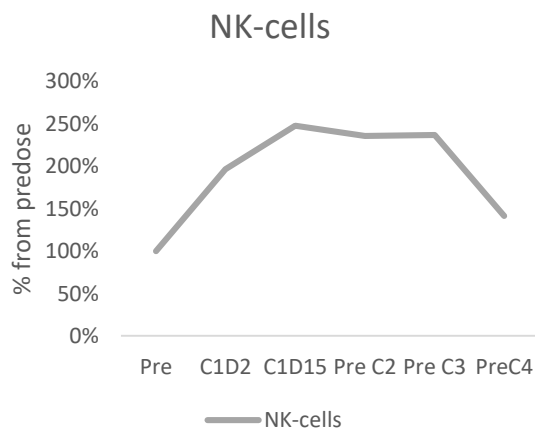
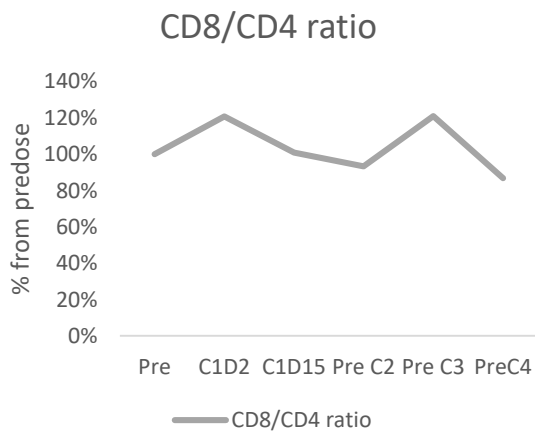
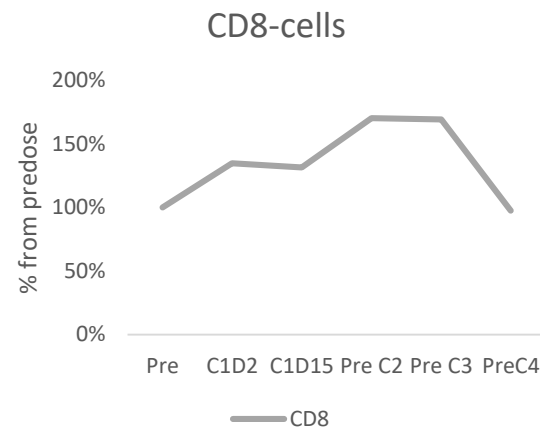
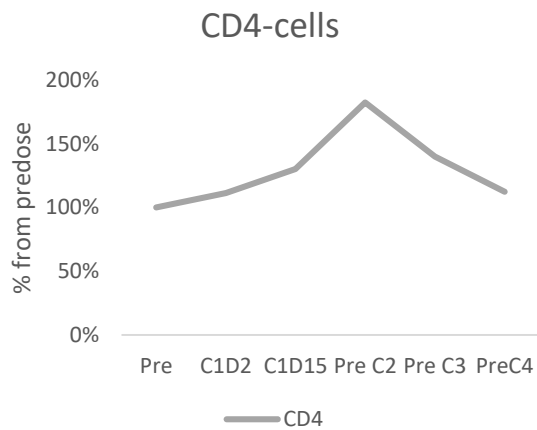
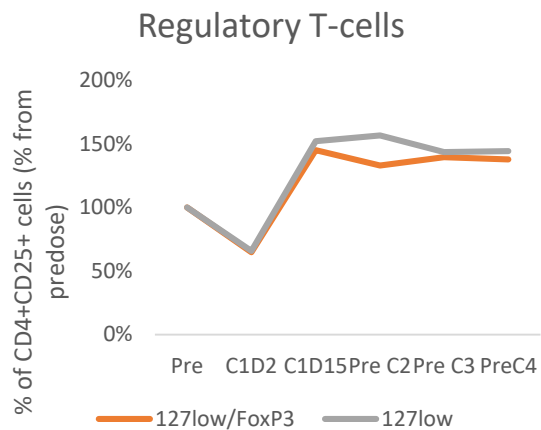
Blood cell type	Prior dose <b>D0</b>	Post dose <b>D2</b>	Post dose <b>D15</b>	Post dose <b>D21</b>
CD8-cells	100%	128%	130%	144%
CD4-cells	100%	118%	122%	142%
CD8/CD4	100%	118%	108%	103%
B-cells	100%	110%	106%	125%
NK-cells	100%	184%	201%	169%
T-regs	100%	80%	132%	118%

↑ -Second dose

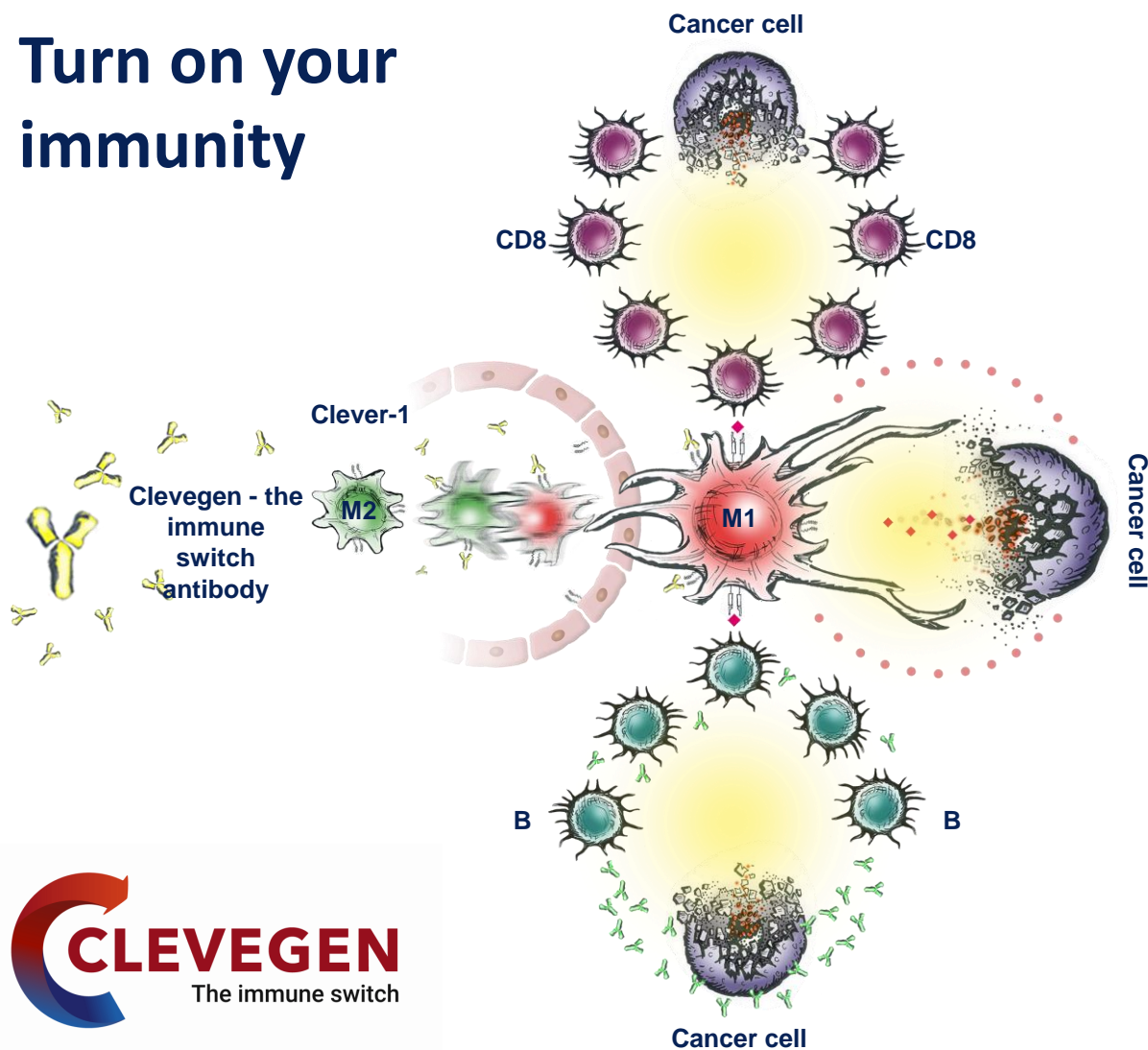
\*These results mirror well with those obtained in tumour bearing mice treated with surrogate Clevegen antibody, and resulted in tumour shrinkage (Viitala et al., 2019)

# STRONG IMMUNE SWITCH POST CLEVEGEN ADMINISTRATION

Blood immune cell changes in partial responder subject



# Turn on your immunity

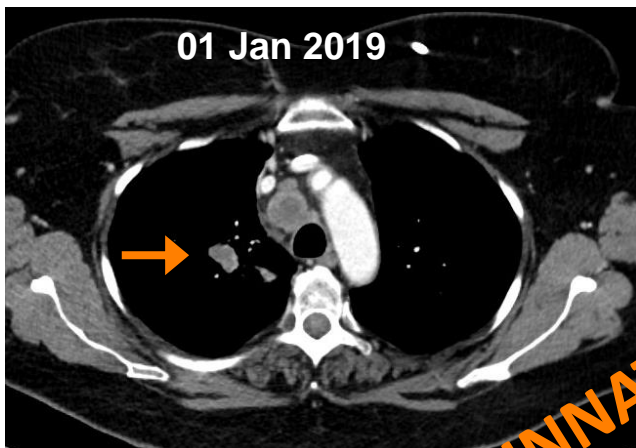


## Observations so far

- Unique target
- Profound immunological effect where wanted
- Does not affect healthy tissue
- Extensive IP coverage
- Liquid biopsy possibility
- Does not lead to T cell exhaustion in mice
- No signs of toxicity in primate (100 mg/kg)
- Biological basis for target populations

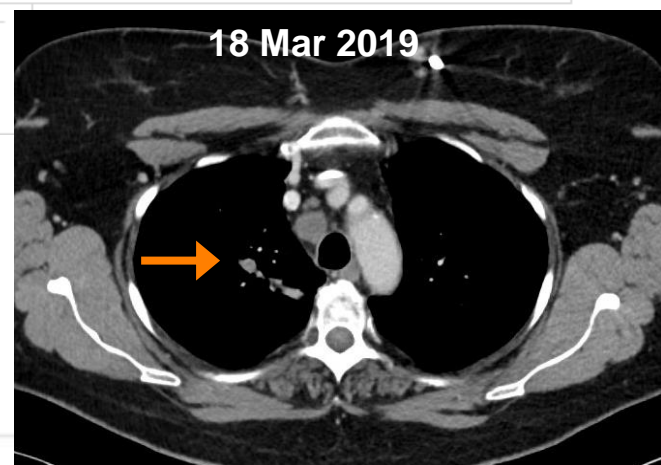
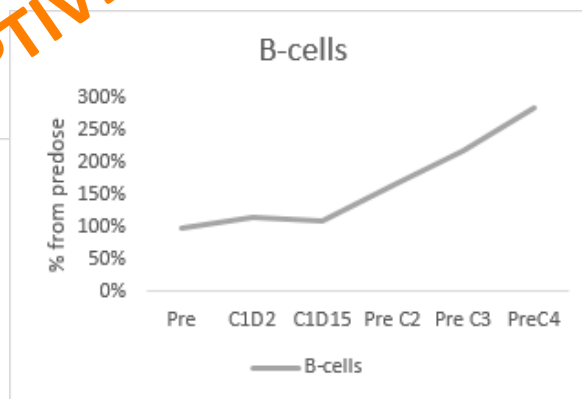
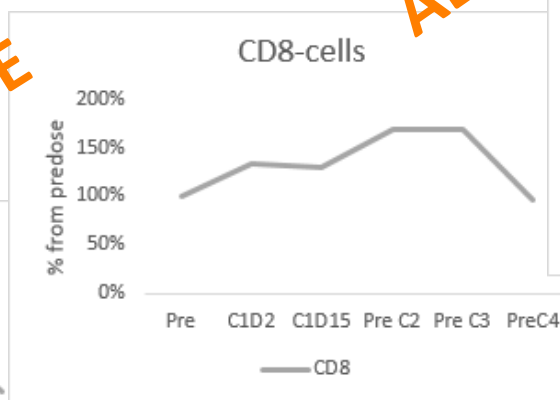
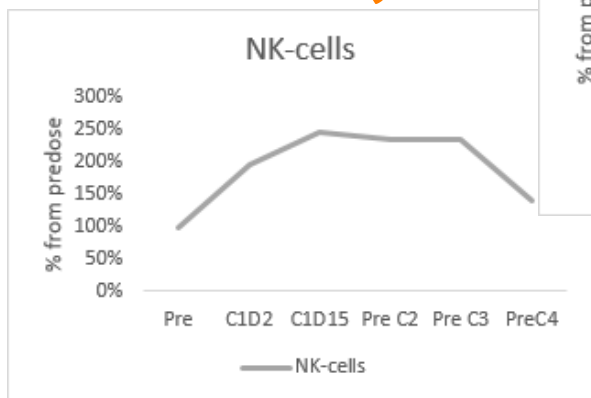
# PERFORMANCE OF THE HUMANIZED ANTIBODY IN MAN

Concept proven in vivo in man – Re-activation of the host immune response



INNATE

ADAPTIVE



## CLEVEGEN VALUE DRIVERS

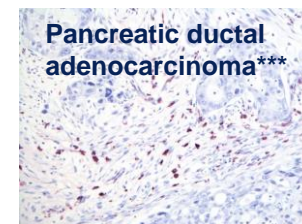
Potential as stand-alone or in combination to combat cancer

### Novel mode of action to remove immune suppression around tumours

- Targets unique immune switch molecule Clever-1 on the surface of tumour associated type 2 macrophages (TAM-2)
- No expected abnormalities following *in vivo* studies due to the nature of Clevegen as a humanised antibody and the presence of Clever-1 in normal tissues and physiological processes, supported by good primate safety data

### Maximising treatment success using liquid biopsy for Clever-1 positive monocytes/macrophages

- Low presence of CD86<sup>+</sup> TAMs (M1) and high presence of CD206<sup>+</sup> TAMs (M2) correlate well with aggressive HCC and poor survival outcome (Dong et al., Int. J. Mol. Sci. 2016: 17: 320)
- High presence of Clever-1 positive TAMs is associated with poor survival in colorectal cancer (Ålgars et al. Int J Cancer 2012;131(4):864-73)



### Targeting Clever-1 positive cancer patient populations\* with significant unmet need

Cancer type	Cases/year*	Deaths/year*	Death percentile	Clever-1 positivity**	Potential number of treatments
Colorectal	1 650 000	835 000	51 %	50 %	825 000
Liver	782 000	746 000	95 %	90 %	703 800
Pancreas	338 000	330 000	98 %	90 %	304 200
Ovarian	239 000	152 000	64 %	60 %	143 400
					<b>1 976 400</b>
					<b>TOTAL</b>

\*WHO World Cancer Report 2014 , \*\*Population percentage of Clever-1 positive macrophages in human tumour samples (Source: Company information)

\*\*\*Brownish stain indicates Clever-1 positive TAM's. Courtesy of Dr. Shishir Shetty, The Centre for Liver Diseases, The University of Birmingham, UK



## NEXT CLEVEGEN STEPS

### Clevegen

- Complete part I of the MATINS trial to optimise dosing
- Expand study sites in Europe and US for part II (expansion cohort)
- Continue MATINS data analysis to understand early responder signal from the surrogate markers
- Amend protocol to define optimal cohort populations
- Expand clinical indications (e.g. glioblastoma, breast, head and neck)
- Continue partnering discussions
- Plan manufacturing expansion



**Thank You**

*“Our world is built on biology. Once we begin to understand our biology, it then becomes a technology”*