Faron Pharmaceuticals

(LSE AIM: FARN, NASDAQ Helsinki: FARON)

AGM Presentation, 18 May 2020

CEO Markku Jalkanen

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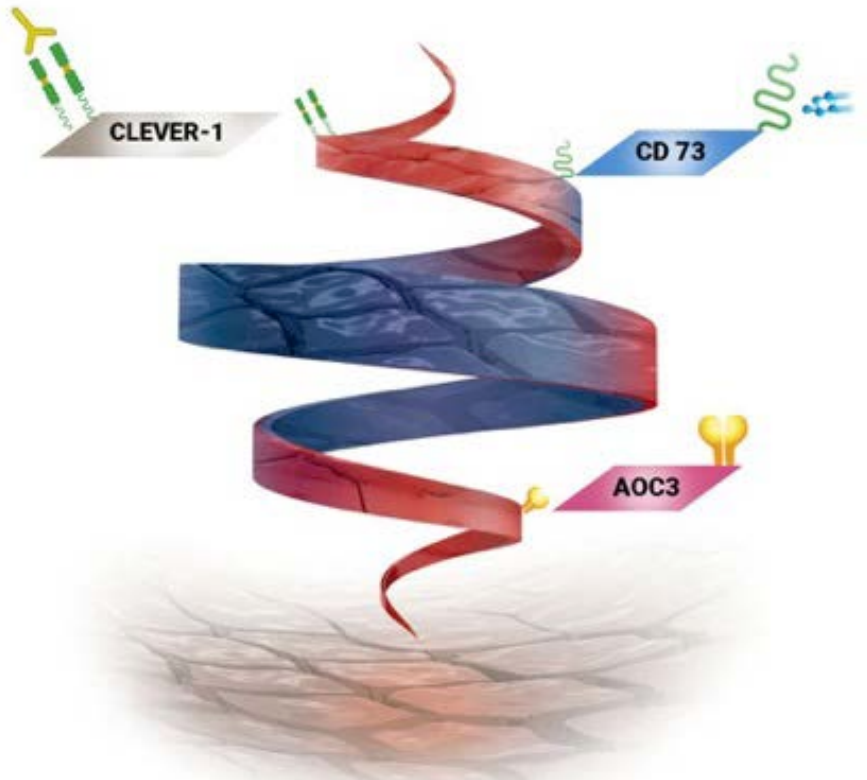
FARON'S PIPELINE IS BASED ON RECEPTORS INVOLVED IN THE REGULATION OF IMMUNE RESPONSES & VASCULAR DYSFUNCTIONS

Immuno-Oncology

Clevegen®

Clever-1 regulates tissue immune status



ARDS & Organ protection

Traumakine®

CD73 controls capillary leakage and escalation of inflammation

AOC3 escalates inflammation and vascular damage*

*Recently in-licensed pre-clinical project

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 IS FOCUSED ON ACTIVATION OF LOST IMMUNITY AND ORGAN FUNCTIONS

Faron is a Finnish based biotech developing first in class therapies in immuno-oncology and organ failure

- Lead cancer immunotherapy program, Clevegen, is a novel anti-CLEVER-1 antibody with the ability to switch immune suppression to immune activation
- Early results from ongoing Phase I/II study in solid tumours show broad effect on immune checkpoints, co-stimulation markers and activation markers.
  - Potential for “combination drug in a single treatment”
  - Smarter selection of combination treatment can reduce costs, patient burden and increase clinical efficacy
- Clevegen has been well tolerated and demonstrated promising clinical anti-tumour activity in several tumour types
- Pipeline includes Traumakine (intravenous interferon beta-1a) developed to prevent vascular leakage in acute respiratory distress syndrome (ARDS)
  - Currently in global REMAP-CAP and WHO SOLIDARITY clinical trials including COVID-19 patients
- Faron has been listed on London AIM (FARN) since 2015, and on the NASDAQ Helsinki (FARON) since 2019

KEY PIPELINE HIGHLIGHTS – ALL MAJOR GOALS ACHIEVED
(including Post Period-end)

Clevegen

- Part I of MATINS trial completes with switch in immune cell profiles towards increased immune activation confirmed in cancer patients and good tolerability at all dosing levels
- Down regulation of a range of major inhibitory immune checkpoints (PD-1, PD-L1, CTLA-4, etc)
- First target lesion responders observed (CRC and melanoma)
- Data monitoring committee recommends rapid expansion of MATINS into additional tumor types
- AGC Biologics selected to be commercial scale manufacturer

Traumakine

- INTEREST trial results explained by molecular interference of concomitant corticosteroid use
- FDA acceptance of new clinical study plan for Traumakine in ARDS patients
- Currently in two major global trials investigating potential in COVID-19 patients

AOC3 antagonist platform technology

- Rights acquired for potential new use of AOC3 inhibitors

KEY FINANCIAL & CORPORATE HIGHLIGHTS
(including Post Period-end)

Financial

- Successfully raised €15.6m gross (€14.5m net) through several fundraises during 2019
- Continued tight cash management into 2020
- Cash balance of €7.1m on 31 December 2019 (2018: €4.1m)
- Operating loss of €13.3m (2018: €20.1m)
- Net assets of €1.6m on 31 December 2019 (2018: €0.4m)
- Recent €14.0m cross equity round will finance the Company to H1-2021

Corporate

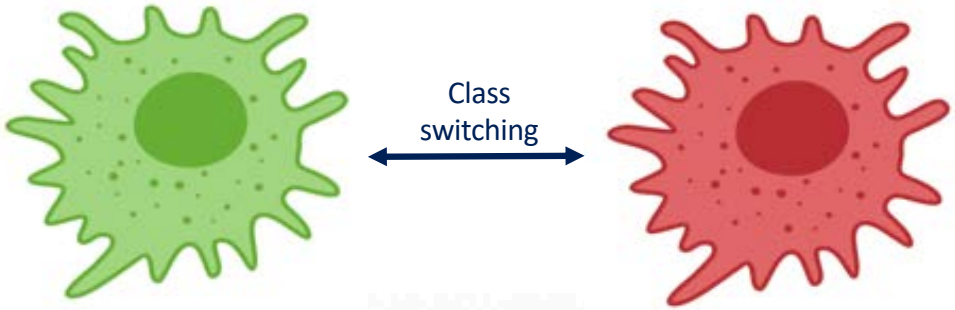
- Voluntary salary and fee savings by Board, CEO and personnel continued into Q1/2019
- Structural alignment of management team with current objectives
- Alignment of finance and funding (New CFO Toni Hänninen; Yrjö Wichmann to VP, Financing and IR)
- Dual listing NASDAQ First North Helsinki in December 2019

Turn on your immunity

CLEVEGEN
The immune switch

MACROPHAGES AS GENERALS OF ANTI-TUMOR IMMUNITY

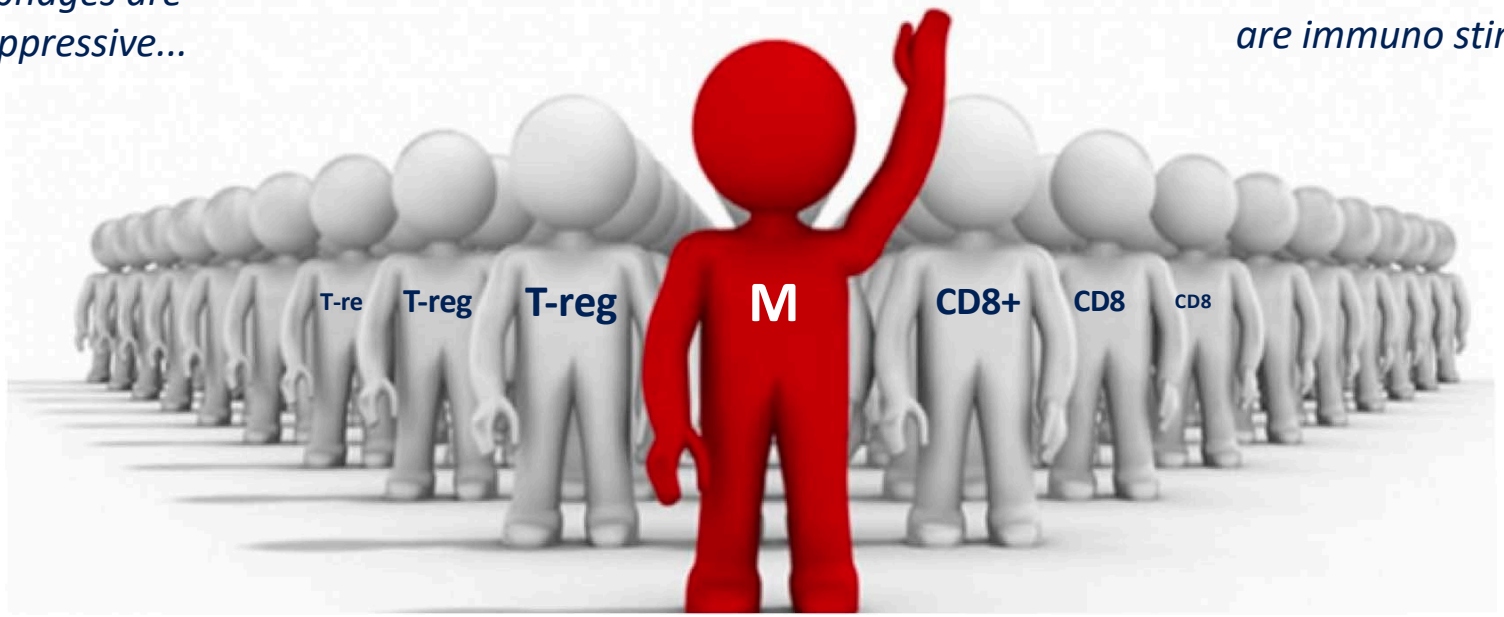
Pro-tumor (M2)
IL-10, TGFβ
Low MHCII



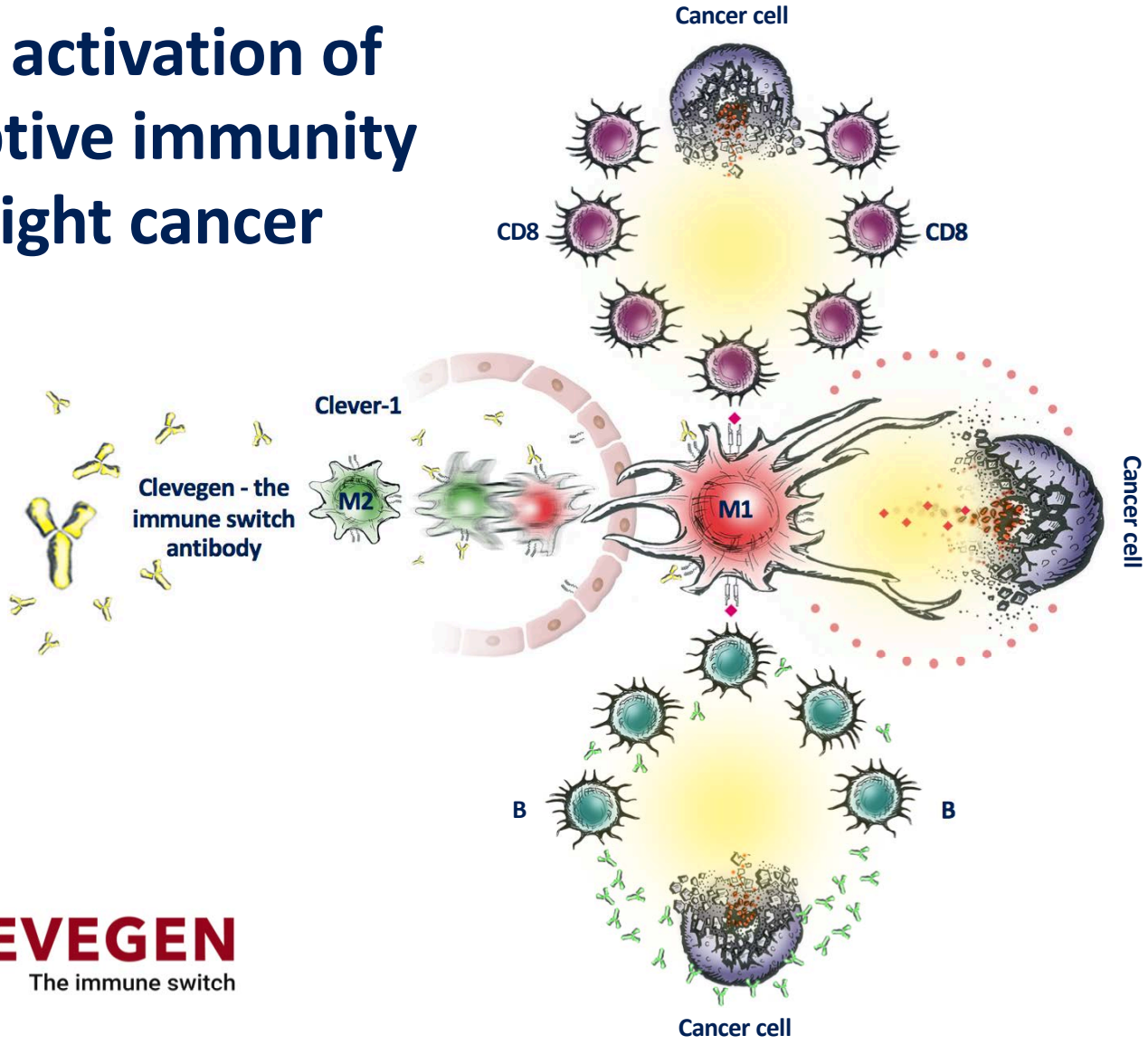
Anti-tumor (M1)
IL-12, TNFα
High MHCII

M2 macrophages are immunosuppressive...

... while M1 macrophages are immuno stimulatory



Only activation of adaptive immunity can fight cancer



CLEVEGEN
The immune switch

MATINS STUDY EXPANSION TIMELINES

Part II ongoing

MATINS

Part I (dose finding)		Part II expansion	Part III expansion
Dose escalation 4 dose levels n=2 at each dose level total n=8 HCC, PDAC, OC, melanoma, CRC	Allocation to all 4 dose levels n=2 at each dose level total n=8 HCC, PDAC, OC, melanoma, CRC	HCC n=10	HCC
		PDAC n=10	PDAC
		OC n=10	OC
		Melanoma n=10	Melanoma
		GC & CC n=10	GC & CC
(+ 20 mg / kg dose level) + 0.1 mg / kg dose level n=2 at each dose level Total n=12	n=5 at each dose level total n=30	CRC n=10	CRC n =19
		Uveal melanoma n=10	UM
		Gastric Adenoca n=10	GA
		BC(ER+) n=10	BC(ER+)

- Safety ✓
- Surrogate efficacy ✓

→

- Cohort selection ✓
- Initial efficacy ✓

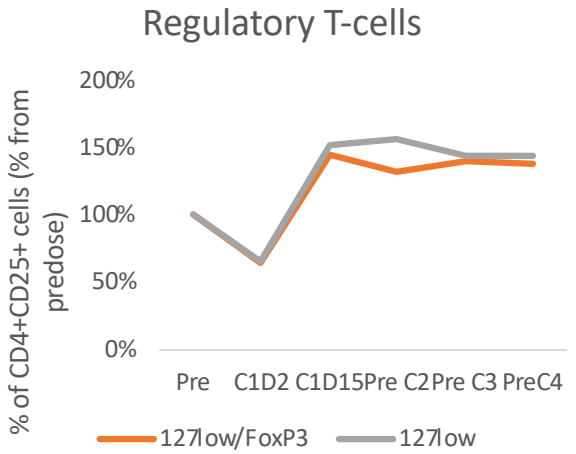
→

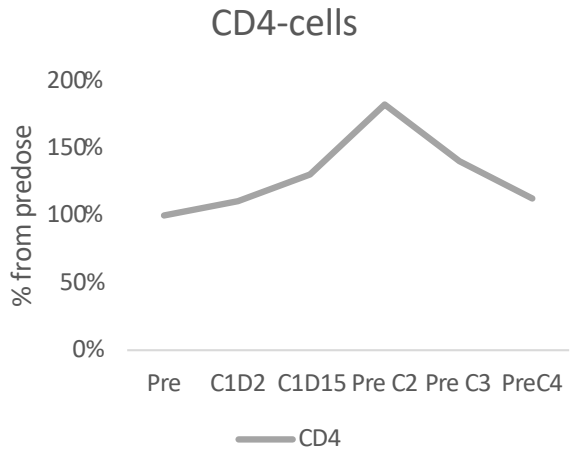
- Cohort expansion
- Clinical proof of concept

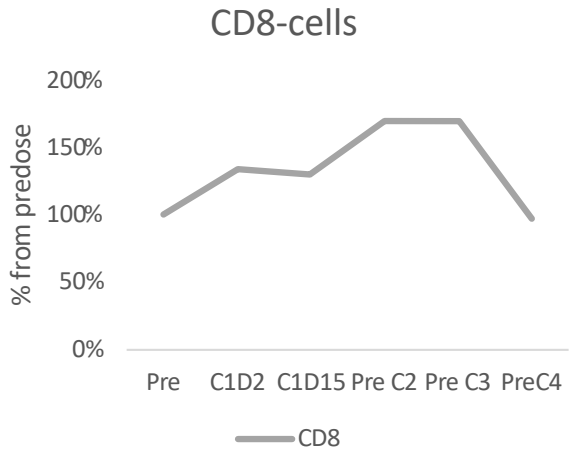
Q4'2018 – Q1'2020 | Q1'2020 – Q3'2021 | Q4'2020 – Q2'2023

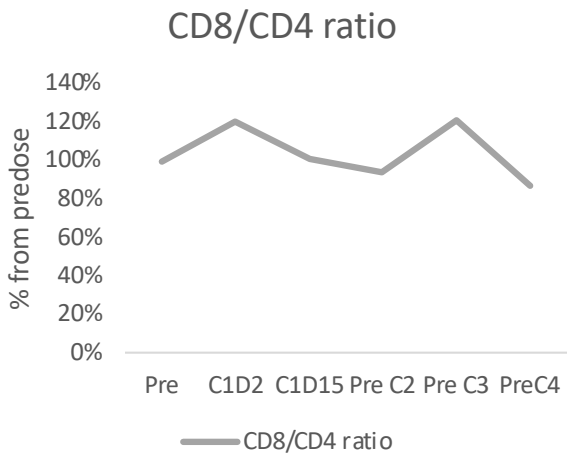
STRONG IMMUNE SWITCH POST CLEVEGEN ADMINISTRATION

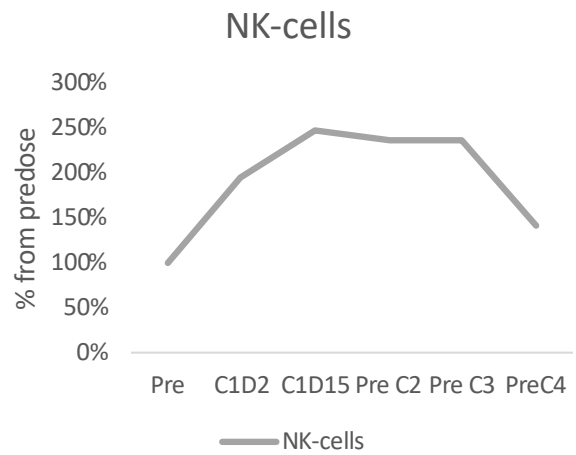
These changes coincided with metastasis shrinkage of CRC patient tumours

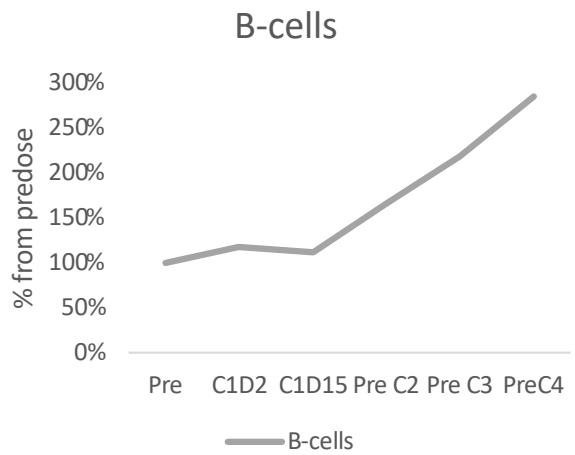








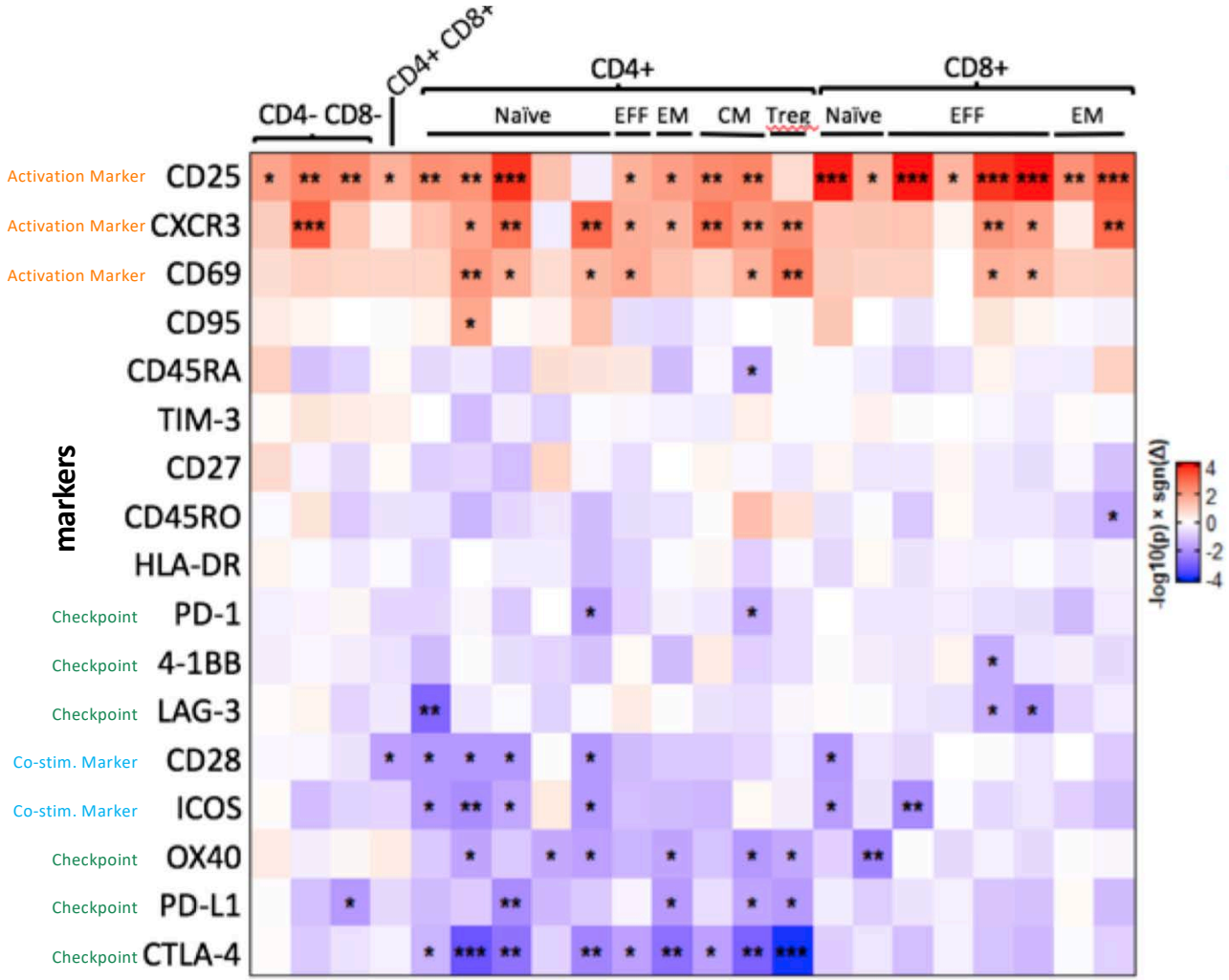




Note: Data shown from metastatic colorectal cancer partial responder in MATINS study

CLEVER-1, MASTER REGULATOR OF IMMUNITY

Anti-Clever-1 treatment downregulates all major checkpoints on T cells



EFF = Effector
EM = Effector memory
CM = Central memory
Treg = T regulatory

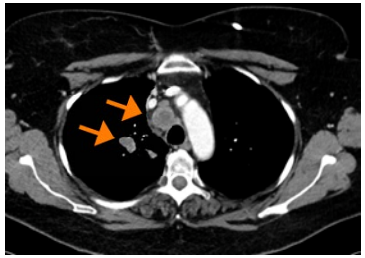
* P < 0.05
** P < 0.01
*** P < 0.001

Conclusion:

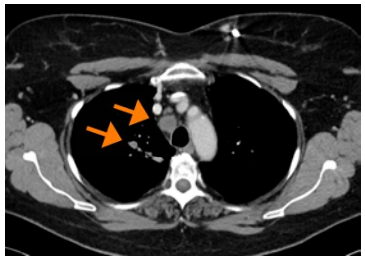
- Clevegen could outperform current immune check point treatments (anti-PD-1, PD-L1, CTLA-4, etc.) and, as monotherapy, provide permanent immune stimulation against various cancer types
- Sales of the current IO cancer treatments in 2019 were $15+ billion

INCREASING NUMBER OF RESPONDING CANCERS

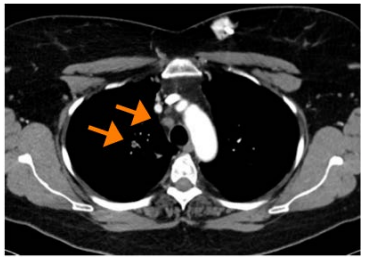
Colorectal cancer



baseline



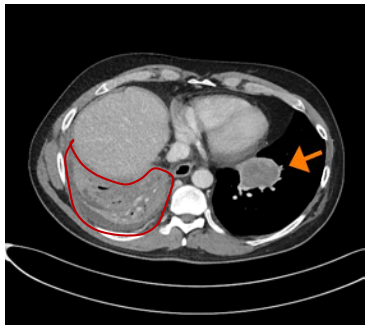
10 weeks



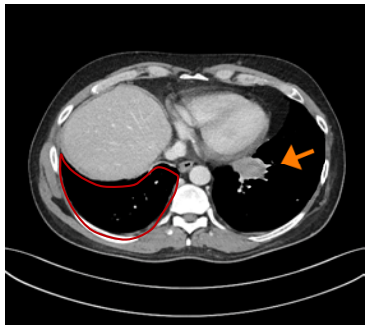
30 weeks

Arrows point shrinking lung metastasis in MSI low CRC patient. Treatment initiated after six lines of therapy

Cutaneous melanoma



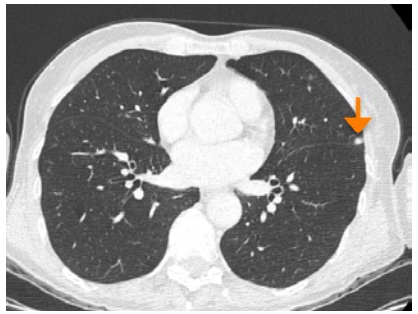
baseline



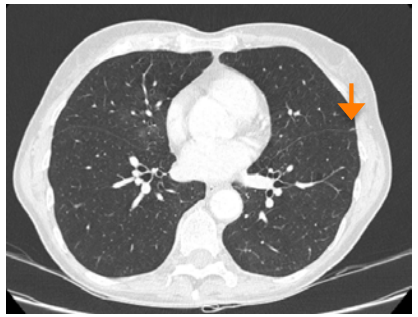
6 weeks

Arrow points shrinking lung metastasis. Note the clearance of pleural effusion (red circle). Treatment initiated after four lines of therapy including ipilimumab/nivolumab

Ovarian cancer



baseline



10 weeks

Arrow points shrinking lung metastasis. Treatment initiated after six lines of therapy including pembrolizumab

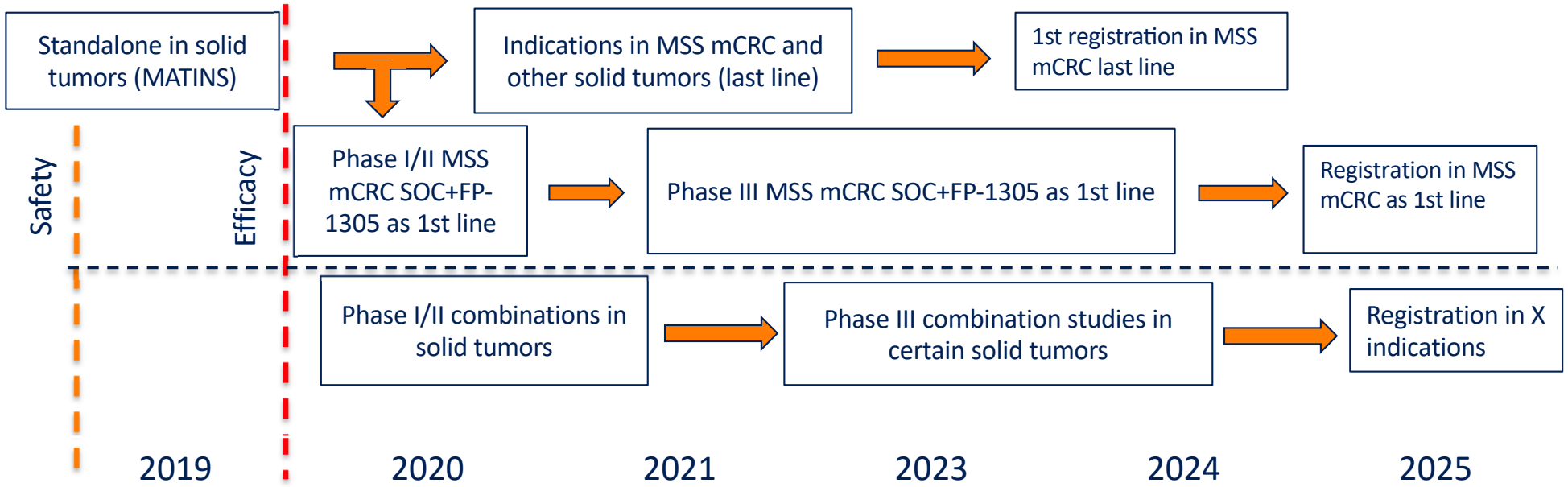
CLINICAL CLEVEGEN SUMMARY

MATINS Part I outcome

- No safety concerns
- 2 partial responses (PR): one in MSI neg CRC (0.3mg/kg) and one in melanoma (1mg/kg)
- 1 pseudo-progression in ovarian cancer (3mg/kg), followed by shrinking of target lesions and disappearance of some off-target lesions
- 7 stable disease (SD)/or mixed responses, some still under evaluation
- Clinical response is statistically associated with an increase in peripheral natural killer (NK) cells and B cells and an increase in plasma interferon gamma levels

Recommendation from study data monitoring committee to rapidly expand study into all cancer cohorts in the study protocol

FOCUSED CLINICAL DEVELOPMENT STRATEGY INITIATED WITH CRC



- Development initiated as a stand alone in solid tumors with Clever + and no treatment options
- Moving into other solid tumours and 1st line settings after safety and tolerability has been established
- Combination studies run by partner(s) if satisfactory offers are met

CLEVEGEN VALUE DRIVERS

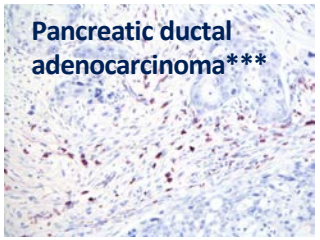
Provides stand-alone or combination therapies to combat cancer

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 toxicities or abnormalities (e.g., cytokine storm, acute infusion reaction, etc), supported by good primate and human safety data

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

- Low presence of $CD86^+$ TAMs (M1) and high presence of $CD206^+$ 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)



Examples of targeted Clever-1 positive cancer patient populations*

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	
					1 976 400	**TOTAL**

Commercial upside could be significant as safety profile is better than with many existing IO products and treatment is targeting selected patients

*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

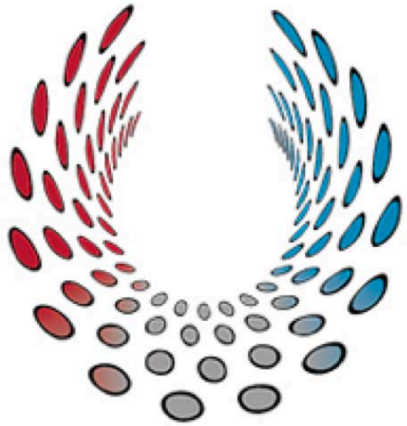
NEXT CLEVEGEN STEPS

Clevegen: Accelerate MATINS regulatory pathway by

- Expanding study sites in Europe and US for Part II and III (cohort expansions)
- Accelerate expansion cohorts, initiated with CRC
- Seeking regulatory end of phase II advice for BLA/MAA pathway
- Applying for Breakthrough (FDA) and Prime (EMA) status
- Continuing partnering discussions
- Executing manufacturing expansion

FARON

INTERFERON-BETA TREATMENT OF ARDS AND OTHER ISCHAEMIC REPERFUSION INJURIES



TRAUMAKINE

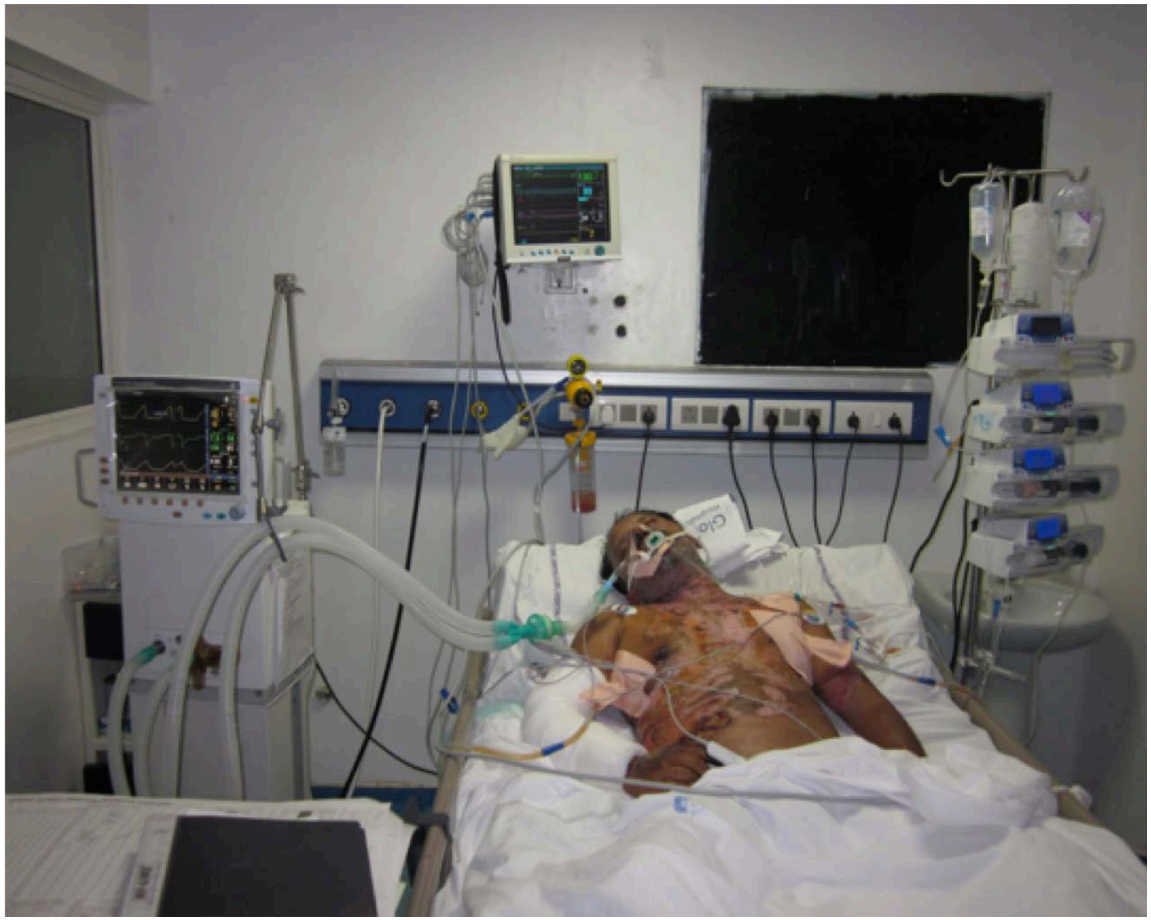
ACUTE RESPIRATORY DISTRESS SYNDROME (ARDS)

A leading driver of mortality in influenza, pneumonia, sepsis, and major trauma

ARDS is an inflammatory lung injury leading to vascular leakage filling the lungs with fluid – "drowning from within"

The burden of ARDS

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

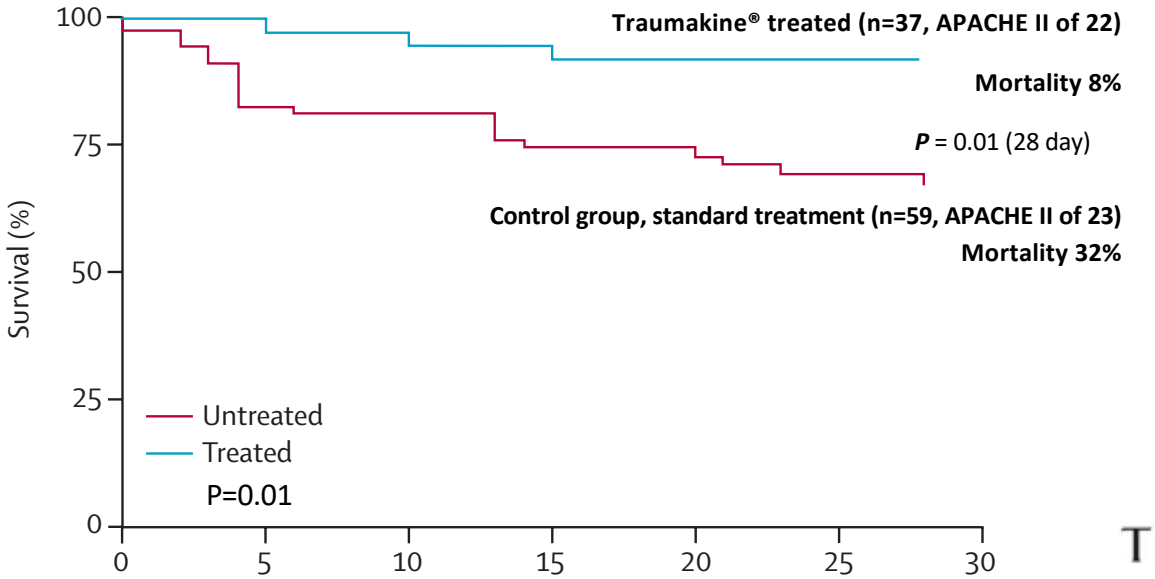


1) Bellani et al. JAMA 2016, 2) Cavalcanti et al. JAMA 2017, 3) Rubenfeld et al. NEJM 2005, 4) Herridge et al. NEJM 2011; 364:1293-304, 5) Herridge et al. ICM 2016;42:725-38

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[1]



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

1) Of the 37 patients treated with Traumakine®, 32 were diagnosed with ARDS (PaO2/FiO2 ≤200 mmHg) and 5 patients were diagnosed with ALI (PaO2/FiO2 ≤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 TRIAL (*INTEREST* STUDY): DESIGN & RESULTS

Multi center, double blind, 1:1 randomized, pan-European trial[1,2]

N=301 (296 dosed)

Eligible patients

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

Dosing regimen
IV once daily for 6 days

FP-1201-lyo 10 µg

Primary analysis: all-cause mortality & VF days

FDA required endpoint: all-cause mortality & VF days

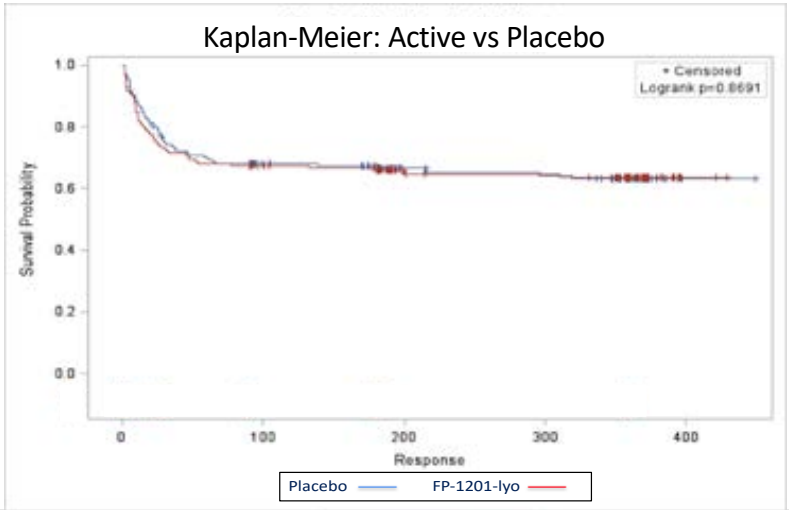
All-cause mortality

All-cause mortality

Placebo

0 28 90 180 360

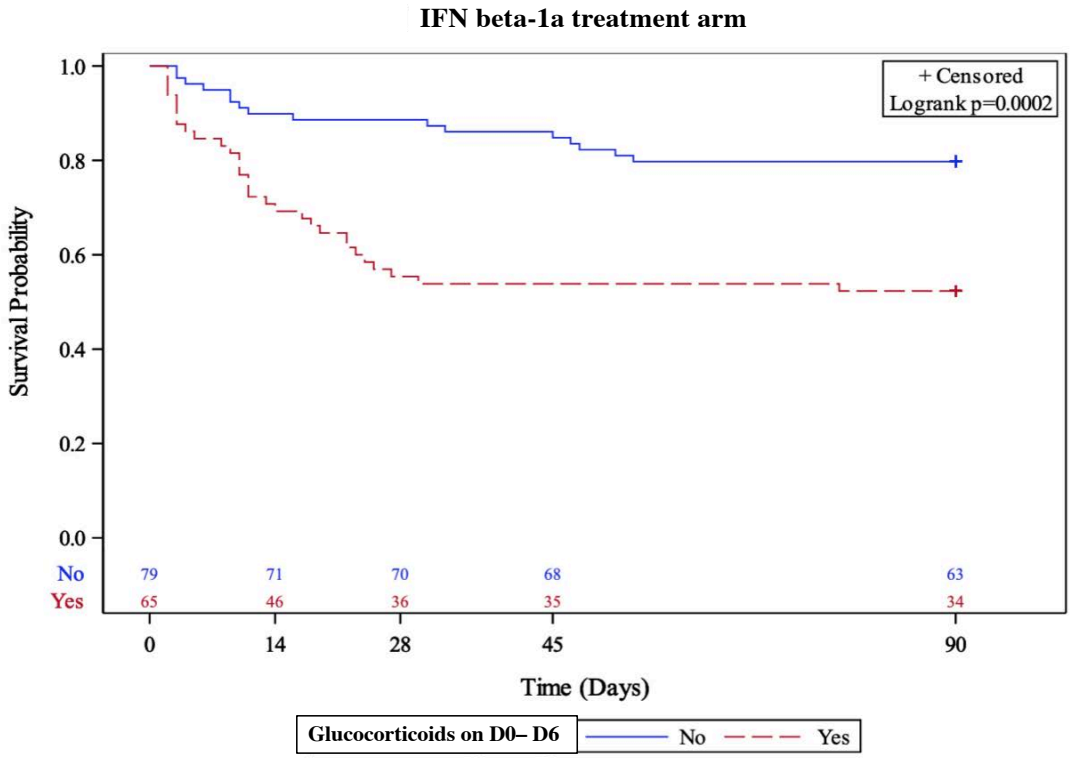
- No difference between groups
- Placebo mortality low due to pneumonia without organ damage
- Post hoc analysis suggests that concomitant steroid use blocks interferon beta activity and increases mortality risk **by 7x**
- Post hoc analysis also suggests that **Traumakine effective without concomitant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



1) Clinicaltrials.gov. https://clinicaltrials.gov/ct2/show/NCT02622724; 2. Bellingan G, et al. Trials 2017;18:536

CONCOMITANT CORTICOSTEROID USE INCREASES MORTALITY

Post hoc propensity-matched analysis of INTEREST trial data base of the active arm[1]



Patients without concomitant steroid use

Patients with concomitant steroid use[1]

(1) Steroids reduce the efficacy of Traumakine by reducing its inferior-beta activity

[1]Manuscript accepted for publication in Critical Care Medicine, a leading ICM journal

FUTURE TRAUMAKINE STEPS

Traumakine: Supporting next steps

- Support COVID-19 global response with Traumakine participation in REMAP-CAP and WHO SOLIDARITY trials
- Finalise new study plan for US post FDA acceptance of study design and protocol
- Study initiation post external funding
- Continue interactions with key ICU opinion leaders to minimize corticosteroid use in ARDS patients
  * The Company noted a recommendation made by WHO in January 2020 that steroids should not be used on coronavirus infected patients: https://www.who.int/publications-detail/clinical-management-of-severe-acute-respiratory-infection-when-novel-coronavirus-(ncov)-infection-is-suspected
- Seek publications in leading peer-reviewed journals
- Re-establish Traumakine manufacturing

KEY INVESTMENT HIGHLIGHTS

1 Lead IO Program, Clevegen (FP-1305), is Potentially First-in-Class	• Advancing promising first-in-class immuno-oncology program, Clevegen, which appears to reactivate the immune system against immunosuppressive tumors • Clevegen targets CLEVER-1 positive Tumor-associated Macrophages (TAMs) and converts highly immunosuppressive M2 macrophages to immune stimulating M1 macrophages
2 Significant Clinical Progress to Date, With Excellent Safety Data	• The MATINS study is the first-in-human open label Phase I/II clinical trial with an adaptive design to investigate the safety and efficacy of Clevegen in selected metastatic or inoperable solid tumors • Good tolerability at all dosing levels without dose limiting toxicity, leading to the announcement of the first expansion cohort in CRC patients in Jan'20, where there is a significant unmet need and a near-term path to approval
3 Biomarker Data Highlights Clevegen's Potential	• The MATINS trial has revealed patients' immune activation: increased circulating CD8+ T cells and CD8+/CD4+ ratio, decreased regulatory T-cells (T-regs) and/or a substantial increase in mobile natural killer (NK) cells in the blood • The response curve to treatment has revealed a "textbook" innate and adaptive immune response, highlighting the program's potential in earlier lines of treatment
4 Blue-Sky Upside as Part of Personalized Medicine Approach to Cancer Treatment	• The analysis of checkpoints (also known as exhaustion markers) and activation markers can potentially also be used to guide the best possible checkpoint inhibitor(s) combination treatment with anti-Clever-1 therapy • Cell surface markers like PD-1, PD-L1, CTLA-4, LAG3, and TIM, can then be used to monitor a patient's response to anti-Clever-1 therapy and to evaluate the need for combination therapy in addition to anti-Clever-therapy, and point practitioners towards a bespoke, optimized, solution
5 Upside from Legacy Program, Traumakine, in Development for ARDS	• Faron's pipeline includes Traumakine, in development for the treatment of Acute Respiratory Distress Syndrome (ARDS), a disease with 300,000 cases annually in EU & US, 3 million worldwide and a mortality rate of 30–40% • Factors that led to Phase III failure in 2018 are now well understood and corrected, partnering the program will provide upside

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Thank You

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