#### LEADING THE WAY IN BREAKTHROUGH IMMUNE THERAPIES

## **AGM Presentation**

24 March 2023

CEO Markku Jalkanen CFO Toni Hänninen





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# Year 2022 in Brief

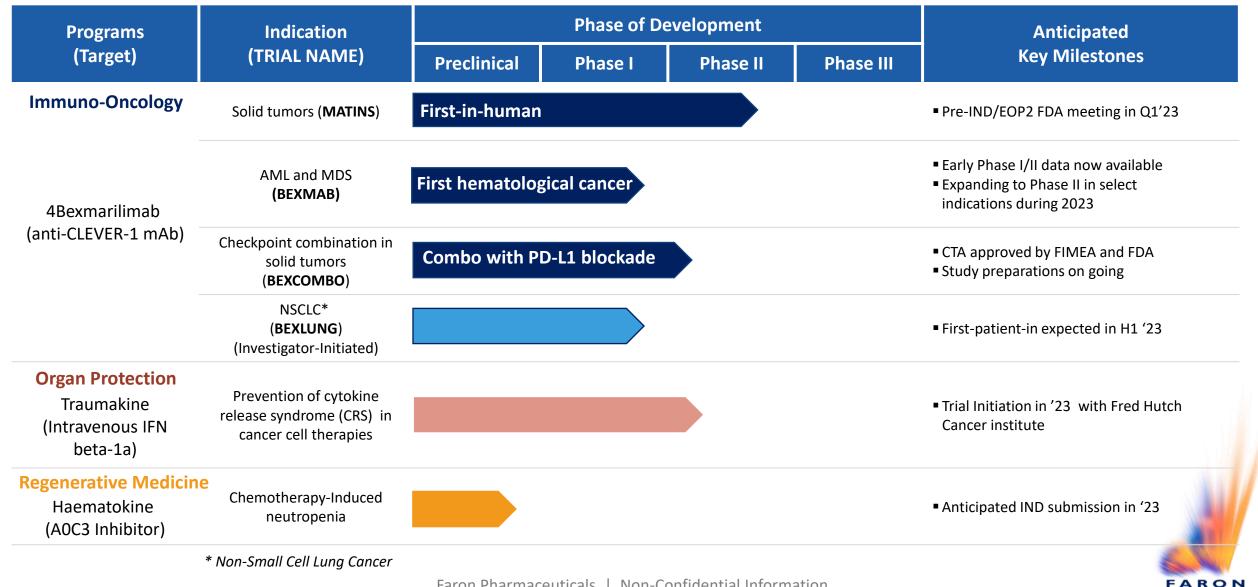
### The Year of Transformation

- Post COVID-19 pandemic the Company re-activated US expansion
- The appointment of the new CMO transformed pipeline, especially the bexmarilimab program
- Successful financing rounds in difficult market conditions allowed further personel development (17 new people altogehter and five new C-level appointments)
- Significant market cap increase opposite to general market trends



# Harness the Power of the Immune System

Modulating the immune system is key to tackling cancer and inflammation



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# **Key 2022 Financial and Corporate Information**

Including post period

- Cash balances on December 31, 2022 of **EUR 7.0 million** (2021: EUR 6.9 million)
- Loss for the period for the financial year ended December 31, 2022 was EUR 28.7 million (2021: EUR 21.2 million)
- Net assets on December 31, 2022 were **EUR -11.5 million** (2021: EUR 2.9 million)
- EUR 13.4 million gross raised in June and October 2022 from new and existing shareholders including The Leukemia & Lymphoma Society <sup>®</sup> (LLS)
- Obtained up to **EUR 30.0** million debt funding from IPF Partners, drew **EUR 10.0** million upon signing in February 2022, further tranches possible under certain conditions
- Post period in January 2023 raised **EUR 12.0 million** gross from new and existing shareholders, including follow on investment from LLS



# **Highly Experienced Team**

Combining tightly the original science and distinguished clinical investigators

#### **Scientific Founder**



Academician & Professor Sirpa Jalkanen, MD PhD Founder & Member of the SAB

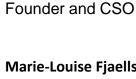
#### Science, Research and **Scientific Founders**

from the University of Turku



#### Management





Marie-Louise Fjaellskog MD, PhD CMO

Toni Hänninen MBA CFO



Juho Jalkanen MD, PhD, MSc Founder and COO

Juuso Vakkuri MA, MSc, EMBA CHRO

Vesa Karvonen LL.M. **General Counsel** 



Erik Ostrowski, MBA Non-Exec Director

#### **Scientific Advisory Board**



Professor Jonathan Knowles, PhD



Pr Christophe Massard MD, PhD



Professor David Adams MD



Professor Tyler Curiel MD, M.P.H.

#### **Program Specific Advisors**



Professor Naval G. Daver; MD



Adjunct Professor Mika Kontro MD, PhD





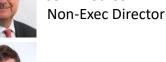
Leopoldo Zambeletti

Non-Exec Director

Anne Whitaker

Non-Exec Director

John Poulos



**Board of Directors** 

Frank Armstrong, MD

Non-Executive

Markku Jalkanen

Founder and CEO

Greg B. Brown, MD Non-Exec Director

Chairman

PhD



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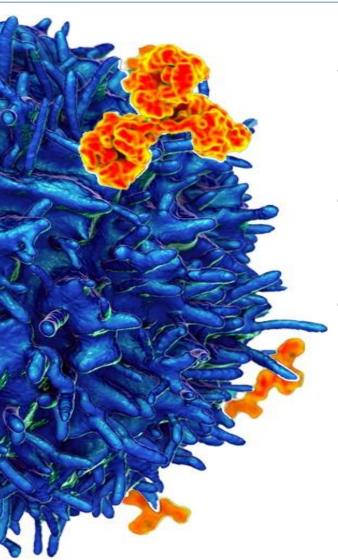
# Outsmarting tumor cells

# "A CLEVER Way to Treat Cancer"



# **The Potential of Bexmarilimab**

#### Removing therapeutic resistance by ignition of host immunity



#### The Rationale

 Bone marrow-born immunosuppressive monocytes and macrophages (myeloid cells) can generate tumor environment helping cancer cells to hide patient's immune system ("Do not show me" -signal)

#### **The Solution**

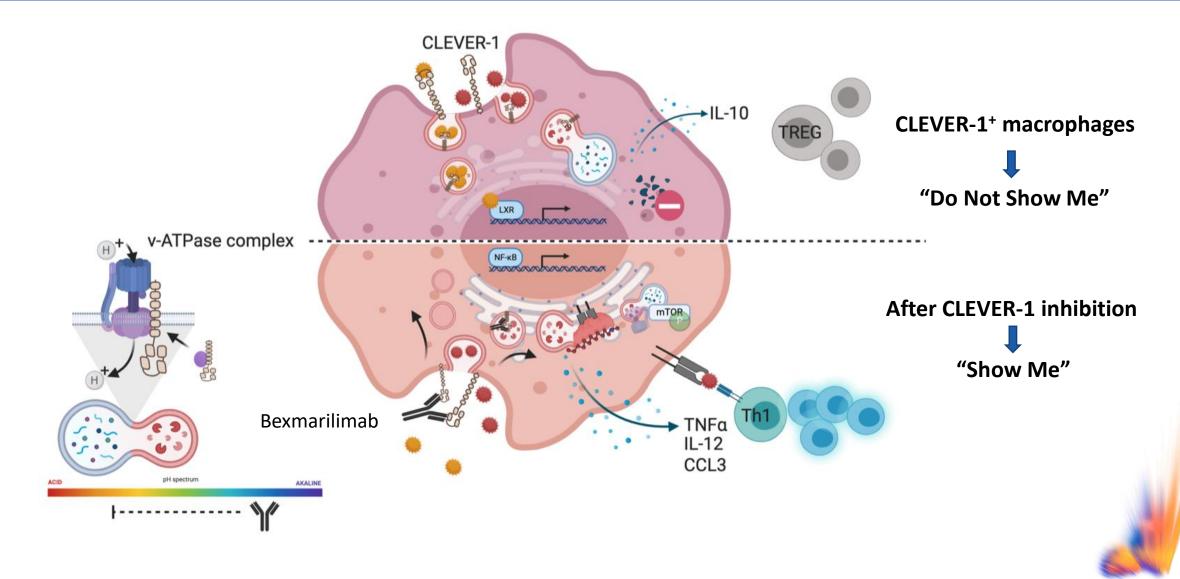
• Bexmarilimab (anti-CLEVER-1) is a first-in-class macrophage-targeting agent reprogramming immunosuppressive macrophages to immune activators ("show me" -signal)

#### The Opportunity: Ignition of host immunity

- To increase overall survival of last-line advanced cancer patients now resistant to all other treatments
- To increase effectiveness of current IO-treatments (e.g. PD-1 blockade) with *bexmarilimab* combination
- Targeting directly cancer cells which express CLEVER-1 (e.g. hematological malignancies)

# **Bexmarilimab Mode of Action**

A macrophage checkpoint to control cancer growth



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# **Bexmarilimab Clinical Program Progress**

#### MATINS laid the groundwork, BEXMAB in progress and BEXCOMBO eyed

#### First-in-human MATINS study has laid the basis for multiple routes to market:

- Bexmarilimab is well-tolerated in 250+ advanced solid cancer patients
- Bexmarilimab dosing and biomarker enrichment revealed
- Bexmarilimab clearly ignites immune reaction in cold tumors



Phase I/II study of *bexmarilimab* on top of SoC in hematological malignancies. Opportunity for accelerated approval.

# MATINS FDA regulatory feedback; PIND/EOP2 meeting Q1 '23 **BEXCOMBO** Advanced indications with CLEVER-1 expression where PD-1 blockade is SoC 1<sup>st</sup> line setting with modest ORR.

#### LAST LINE RANDOMISED

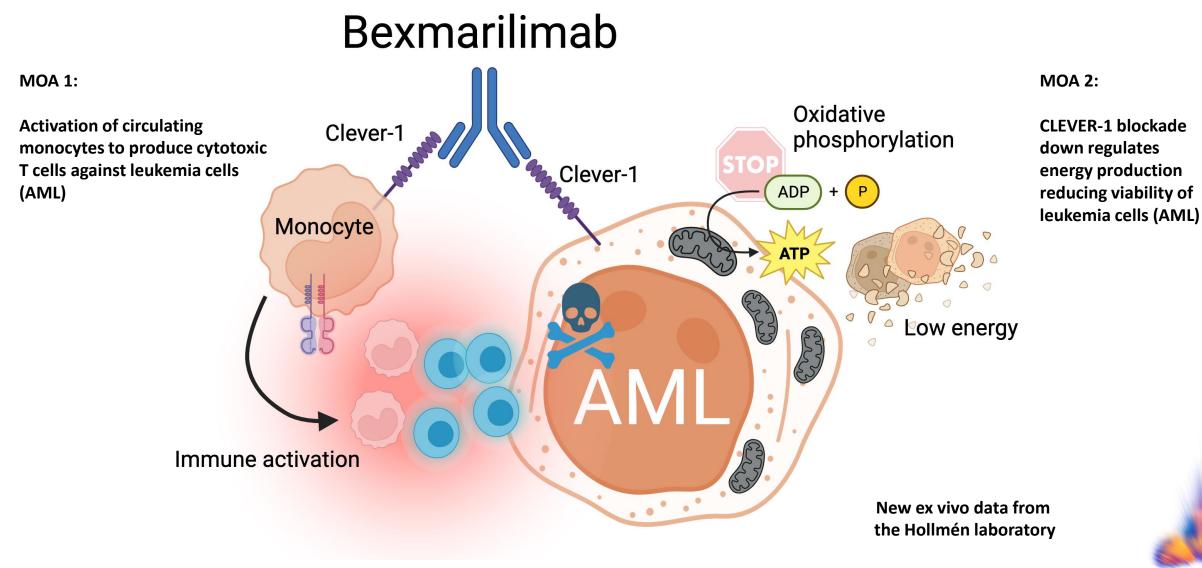
Highest disease control (30-40%), e.g. among bile duct carcinomas



PD-1 blockade naive 1<sup>st</sup> line setting

# **Bexmarilimab Modes of Action to Kill Leukemia Cells**

Limiting oxidative phosphorylation reduces cell viability and results in cancer cell death

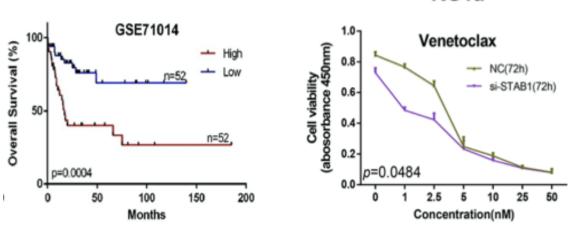


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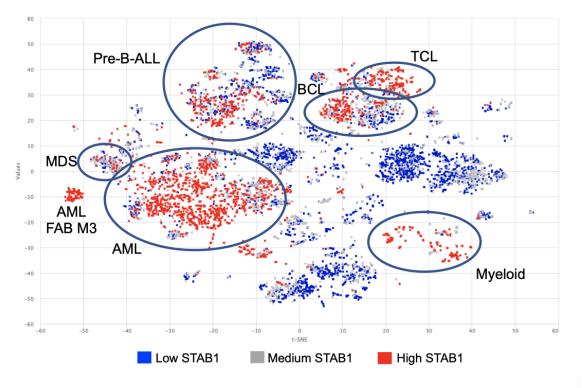
# **CLEVER-1** in Hematological Malignancies

Chuang et al. (Oncotarget, 2015) studied 158 patients with cytogenetically normal (CN) AML and identify *STAB1* (CLEVER-1 mRNA) to be amongst 11 genes differentially expressed in patients with poor response to induction chemotherapy.

Lin et al. (Molecular Therapy Nucleic Acids, 2019) identify *STAB1* to be an independent prognostic factor for CN-AML. Genetic knock-down reduced viability of KG1a AML cells and sensitized them to venetoclax.





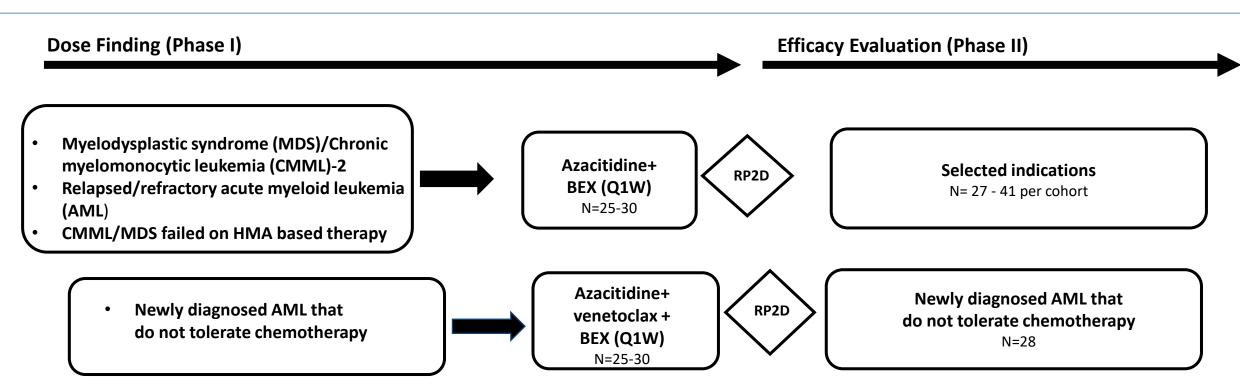


t-SNE plot of *STAB1* expression in primary samples from different hematological malignancies and normal myeloid cells, derived from hemap.uta.fi. (Pölönen et al. Cancer Research 2019)

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# **BEXMAB Study**

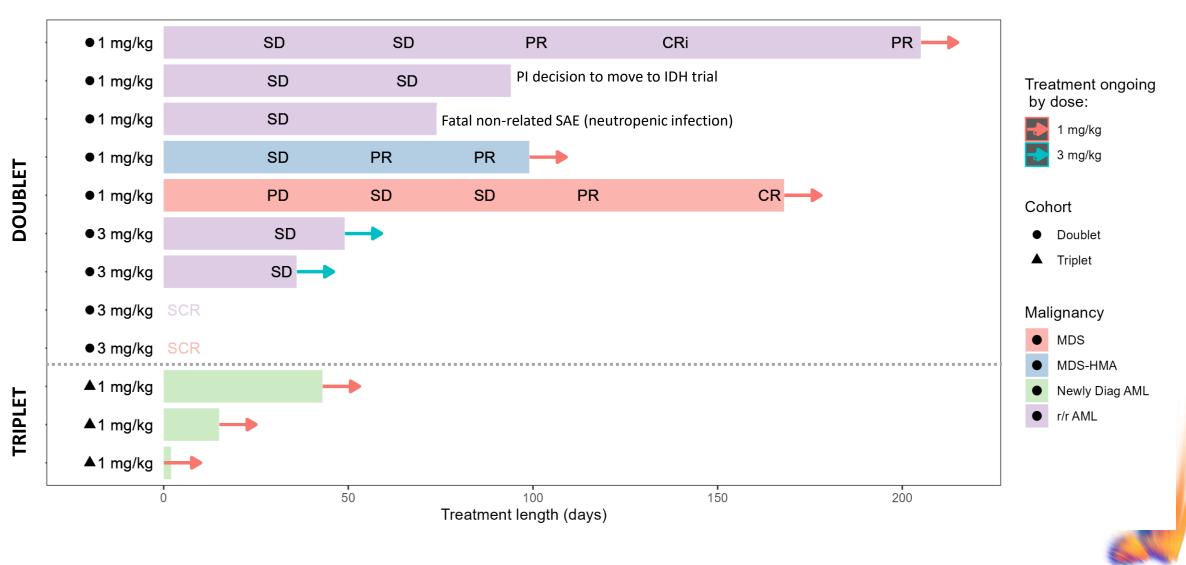
Phase I/II study of bexmarilimab on top of SoC in myeloid malignancies



- Study Design: BOIN (phase I) with 5 patient cohorts; Simon 2-stage design (phase II)
- Preliminary dose levels: 1 mg/kg, 3 mg/kg and 10 mg/kg administered Q1W
- Sites: 4 active in Finland, 4 planned for US (SIV City of Hope, MDA, Yale, UNC FEB/APRIL 2023)
- Amendment to initiate triplet in the US Q1 and align with FDA Project Optimus
- **Dose escalation meeting** for dose level 3 (doublet) FEB2023

# **Responses Observed Across Indications in Doublet**

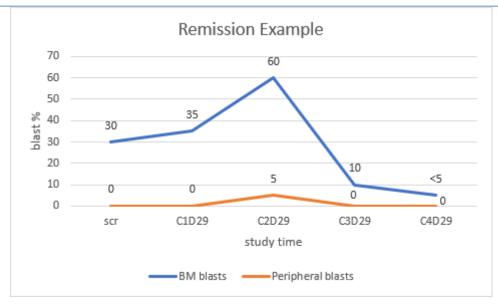
### CRi (r/r AML), PR (MDS HMA), CR (MDS)



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# **Efficacy Example Observed in Myeloid Blast Disappearance**

#### 1.0 mg/kg bexmarilimab Q1W plus azacitidine

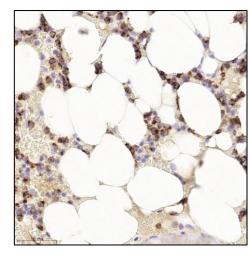


This patient is a prior azacitidine failure (relapsed/refractory AML)

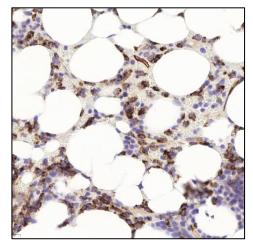
The patient also showed normalised leukocyte blood population indicating bone marrow recovery

Courtesy of Mika Kontro, PI, HUS, Finland (Johannes Dunkel HUS Lab)

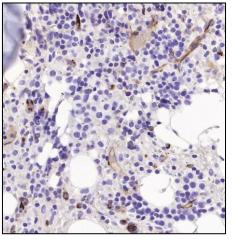
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# **Bexmarilimab Clinical Program Progress**

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Advanced indications with CLEVER-1 expression where PD-1 blockade is SoC 1<sup>st</sup> line setting with modest ORR. PD-1 blockade naive 1<sup>st</sup> line setting

#### LAST LINE RANDOMISED

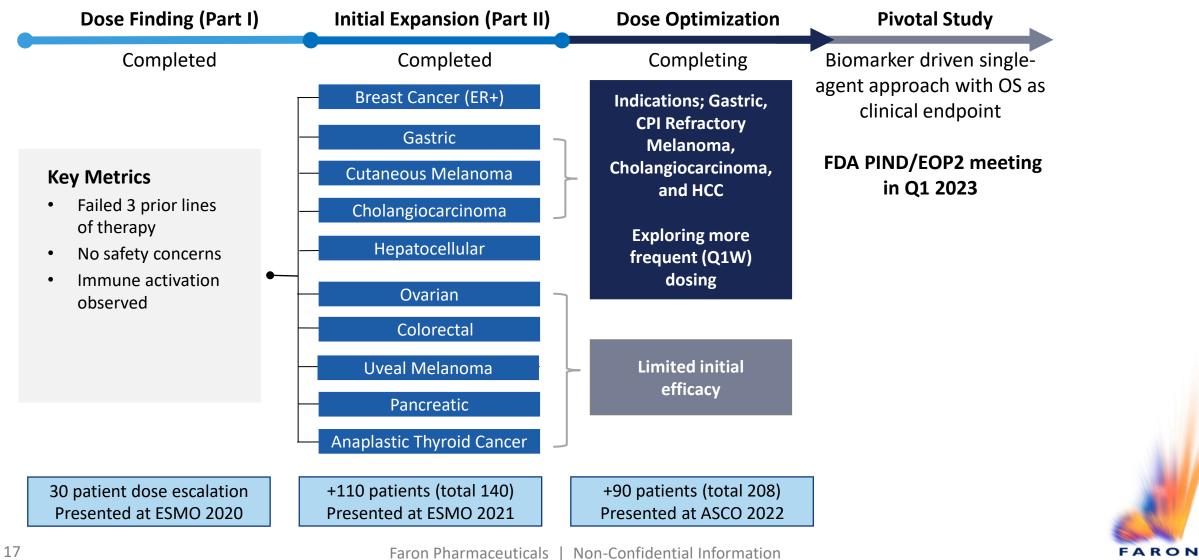
Highest disease control (30-40%), e.g. among bile duct carcinomas

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# MATINS: Phase I/II First-in-human Trial

An extensive evaluation of bexmarilimab in advanced solid tumors



# Summary of Single Agent Bexmarilimab in Solid Tumors

### FDA PIND/EOP2 meeting request sent

#### • Bexmarilimab is well-tolerated

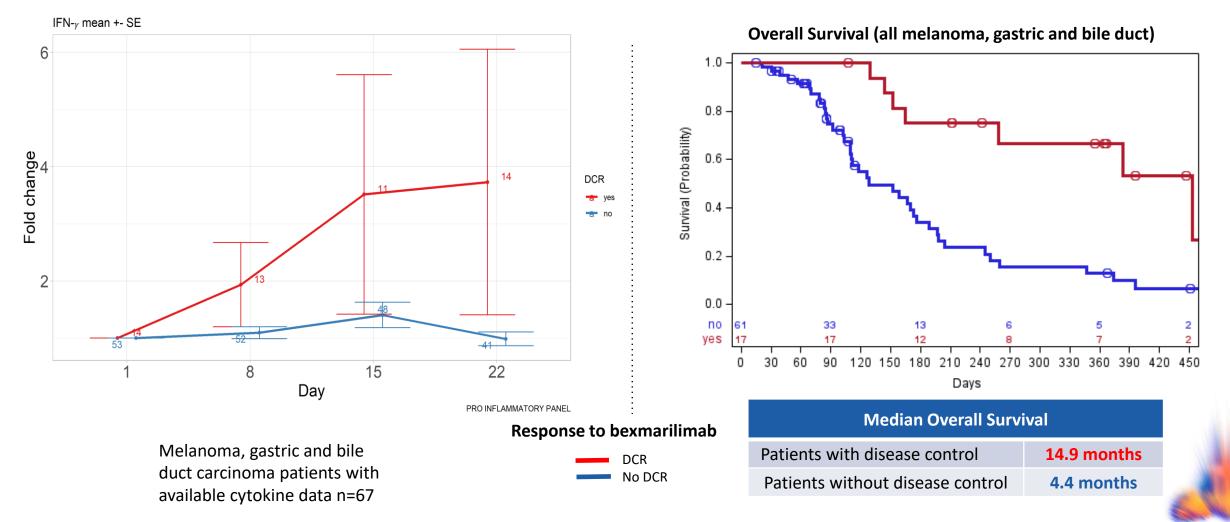
- More than 250 cancer patients treated
- Mostly grade 1/2 events; immune related AEs managed with steroids
- Translational data show immune activation
  - Conversion towards a more M1-like phenotype
  - Reduction of CLEVER-1+ TAMs and T cell activation in paired biopsies
  - Increase of proinflammatory cytokines including IFN-y observed
- Clinical benefit observed as a monotherapy in last-line cancer patients
  - Up to 36% disease control observed in select indications
  - Significant extension of overall survival among responders
- Biomarkers may predict responders
  - Low baseline levels of IFN-y seem to predict for benefit
  - Intra-tumoral TAM CLEVER-1 positivity (IHC) associated with disease control



# **Three-Fold Longer Survival for Patients Achieving Disease Control**

Attributed to bexmarilimab-induced IFN-y increase

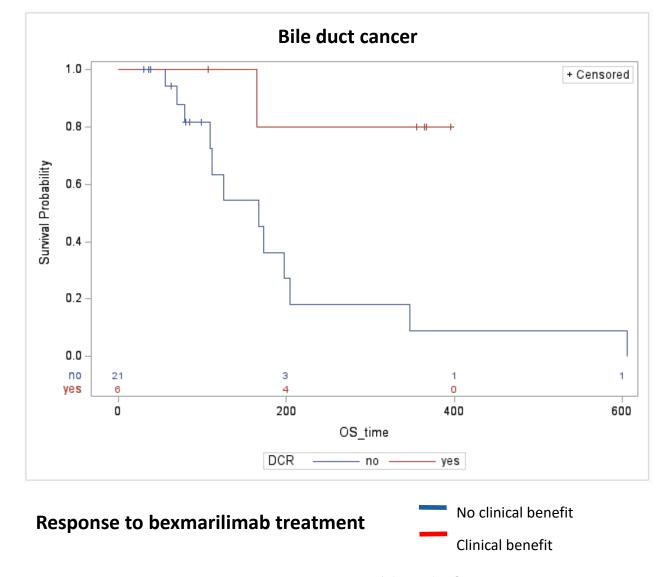
Patients treated with bexmarilimab achieve an immune response (increase in IFN-y) leading to a significant survival benefit.



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# **Overall Survival in Select Indications of Phase I/II MATINS Trial**

Bile duct cancer: candidate for further single agent development





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# Percentage of CLEVER-1+ Cells Associated with Clinical Benefit from Bex

Immunohistochemistry (IHC) staining data from MATINS Phase I/II study

	Number of samples n (%)	Score		A DCR patients n:o 1	n:o 2
		median % (range)	p- value	Elise Contraction	State Law
Clever-1	78 (100)			Gewe	A CALLER AND A CALL
Whole tumor	78 (100)	15 (1-55)			
non-DCR	71 (91)	15 (1-55)	NS		Star 107 The Second St
DCR	7 (9)	20 (13-35)			
Stroma	78 (100)	20 (0-75)		IT I I I I I I I I I I I I I I I I I I	A A A A A A A A A A A A A A A A A A A
non-DCR	71 (91)	20 (0-75)	NS	d sector and	The second second
DCR	7 (9)	20 (5-40)		and the second s	ALC: NO
Intratumoral	78 (100)	5 (0-85)		B non-DCR patients	n:o 5
non-DCR	71 (91)	3 (0-85)	0.038		PERMIT
DCR	7 (9)	15 (0-25)			
PD-L1 CPS	43 (100)	2 (0-100)		lever-	
non-DCR	39 (91)	5 (0-100)	NS		
DCR	4 (9)	1 (0-2)			A STATISTICS AND A STATISTICS
				Carl a state	Grand Constant 223

Score: percentage of CLEVER-1 positive cells over all viable cells, mimicking CPS for PD-L1 staining. Biopsies stained using anti-Clever-1 antibody clone 4G9 by Abnova.

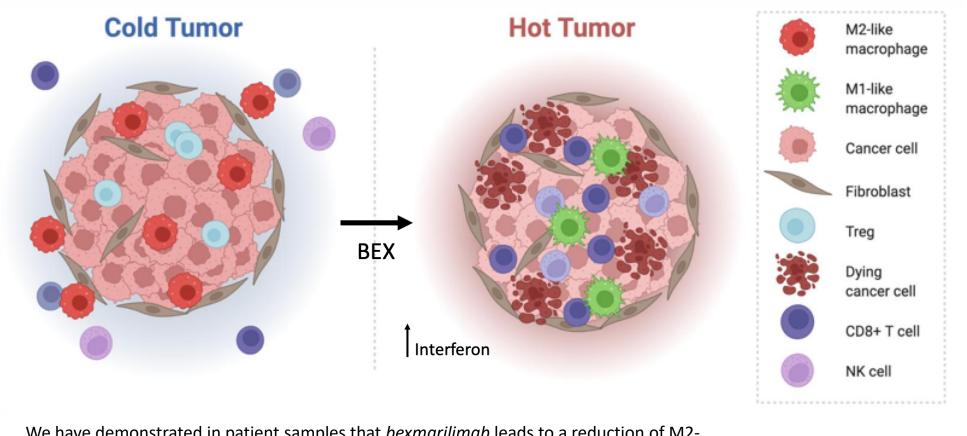




n:o 3

n:o 6

# Bexmarilimab ignites the suppressive tumor microenvironment to support antitumor responses



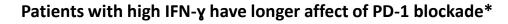
We have demonstrated in patient samples that *bexmarilimab* leads to a reduction of M2like, therapeutic-resistant macrophages. We have also seen an increase in antigen presentation, leading to an increase in IFN-y and the reactivation of T cells (Virtakoivu et al 2021).

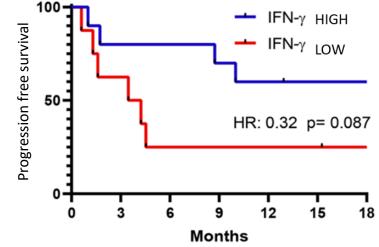


# **BEXCOMBO**

#### Rationale for adding bexmarilimab to PD-1 blockade in solid tumors

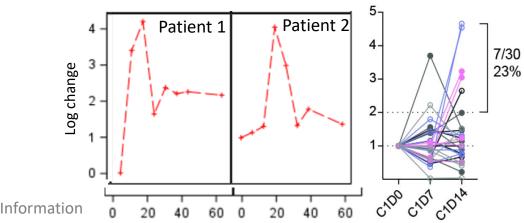
- Most patients (70-80%) do not respond to single agent PD-1 blockade.
- High baseline level of IFN-γ indicates that the immune system is already set to attack cancer cells, and seems required for PD-1 blockade to work
- Bexmarilimab ignites the immune system, thereby turning "cold tumors" (no existing immune activation) into "hot" (existing immune activation) tumors
  - Optimizing the conditions for PD-1 blockade to be effective.
- Preliminary indications are chosen based upon CLEVER-1 expression and modest response to PD-1 blockade
  - HNSCC
  - UC
  - NSCLC





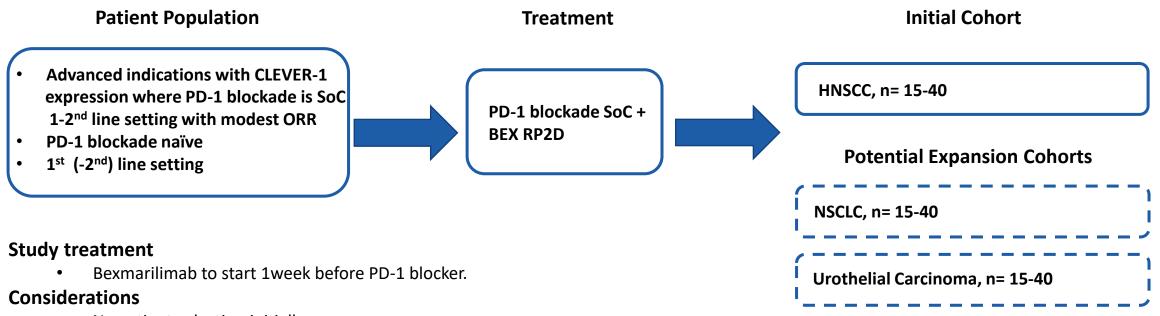
\*Giunta et al. Scientific Reports 2020. Ayers et al. J Clin Invest. 2017

#### BEX increases IFN-γ levels – required for PD-1 blockade response



# **BEXCOMBO Planned Study Run by FARON**

## Phase II (efficacy) study



- No patient selection initially
- Allow for enrichment of subgroups (PD-L1, IFNγ, CLEVER-1)

#### Objectives

- Primary objective: Efficacy
- Secondary objective: Safety/tolerability, Efficacy in subgroups (PD-L1, IFNγ, CLEVER-1)
- Exploratory objective: Immune activation in tumor and blood

#### **Regulatory:**

• CTA approved in Finland (JAN 2023) and by FDA in FEB 2023



# Faron Has a New and Absolutely Unique Cancer Drug BEXMARILIMAB

- 1. We have shown that the drug is well tolerated and not toxic like chemos, in more than 200 cancer patients with no other treatement option left and facing death.
- 2. For the above patients, **we** have shown that 1 out of 3 patients with gastric cancer, liver cancer, melanoma, bile duct cancer or breast cancer benefit from the drug and that we can stabilize the progression of cancer. These patients live 3 times longer than the patients that do not benefit from the drug.
- 3. By detecting the molecule that the drug targets in a tumor biopsy **we** can increase the likelihood of disease stabilization and survival from 1/3 to 2/3 in these same advanced solid tumor patients.
- 4. In blood cancers such leukemia, where the target is abundant, we have even show that we can get rid of cancer entirely.
- 5. To get the drug approved and to the use of patients it needs to be tested in more patients, and for which we have plans ready and/or under execution.

# Near term pipeline related news flow

#### Important value inflection points, especially from BEXMAB study

#### March

KeyStone symposium (poster on macrophage activation after bexmarilimab treatment)

#### April

- FDA feedback on MATINS data and last line single-agent registrational study
- AACR, additional MATINS biomarker data (accepted)
- BEXMAB next dose efficacy read-out from further patients (second doublet and first triplet cohorts)

#### May

• ASCO, bile duct specific data with biomarker/NanoString results from MATINS study pre-post bexmarilimab administration

#### June

- EHA, BEXMAB data
- Further regulatory (FDA) filing with BEXMAB data

#### **Midyear onward**

Additional efficacy data from BEXMAB duplet/triplet cohorts and news on moving r/r AML and MDS-HMA failure to Phase II
according to OPTIMUS



# Thank You

#### Further information:

- <u>www.faron.com</u>
- first.family@faron.com

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