## ACTIVATE YOUR BODY TO DEACTIVATE CANCER

February 2025

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### Harnessing the Power of Macrophages to Conquer Immune Resistance

#### Faron is developing an approach to sensitize treatment resistant cancers to the Standard of Care

Clever-1 is a master immunosuppressive receptor on macrophages which supports tumour growth and metastases
 Bexmarilimab (BEX), first-in-class anti-Clever-1 antibody, removes immune suppression and enhances the clinical benefit of concomitant therapies

#### Bexmarilimab is being developed for high risk MDS, with poor prognosis and high expression of Clever-1

Bex, is currently being developed for high risk MDS (both 1st line and r/r MDS) in combination with Azacitidine and is currently in Phase 2
 Clever-1 is highly expressed in malignant leukemic cells across various blood cancer types such as MDS highlighting its relevance as a therapeutic target

#### r/r MDS represents a substantial market opportunity, for which there are no viable treatment options

- ✓ MDS represents a substantial market opportunity with there being 180-510k patients in the US & EU and 2028 worldwide sales are estimated at \$4.5bn
- ✓ 1st line SoC are hypomethylating agents (HMA), after there is no established 2nd line treatment
- ✓ Patients treated with HMA agents have a poor prognosis with 50% failing to respond to treatment and of the 50% who do respond, 80% relapse in 1-2 years

#### Initial clinical data highlights superiority over existing treatment options in conjunction with a strong safety foundation

- Initial Ph I and II trial data indicates there is superiority over existing treatment options, namely an increase in overall median survival from 5.6 months to 13.4 months and an increase in ORR from 10% to 80%
- ✓ Both read-outs from Faron's Ph II and Ph I / II trial in r/r MDS and 1st line MDS is in Q1 25
- ✓ There is a strong safety foundation with 250+ patients treated

#### Bex has been granted fast track designations in r/r MDS

Faron has received fast track designation for Bex in r/r MDS and there is a clear possibility of accelerated approval with regulatory feedback expected in Q4 2025
 For 1st line treatment, Faron plans on initiating a Phase 3 trial as guided by the FDA

#### Bex is highly applicable in multiple indications and settings

- ✓ Faron is also investigating Bex for advanced solid tumors in combination with chemo and PD-1s
- ✓ 20-30% of all cancers are Clever-1 positive

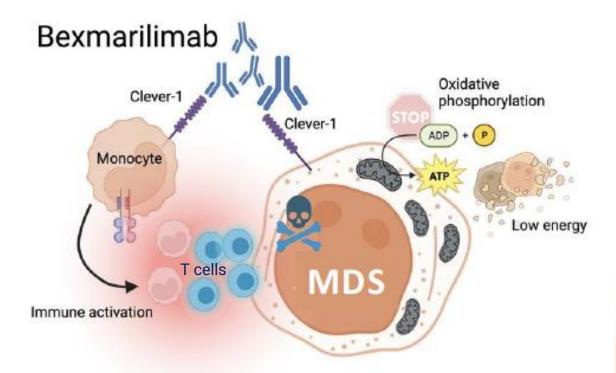
# Best-in-class Macrophage Reprogrammer

## An Overview of the Target

Clever-1 (Common Lymphatic Endothelial and Vascular Endothelial Receptor-1)

#### Clever-1

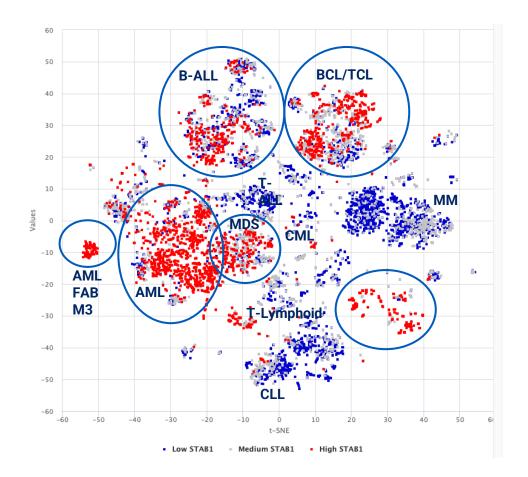
- A scavenger receptor expressed by leukemic myeloid cells and immunosuppressive macrophage populations<sup>1</sup>
- Involved in receptor-mediated endocytosis and recycling of altered and normal self-components
- Regulates leukocyte trafficking<sup>2,3</sup>, inhibits T cell activation<sup>4</sup> and promotes tumor growth <sup>5</sup>
- High Clever-1 expression in cancer associates with poor prognosis<sup>6,7</sup> and contributes to treatment resistance<sup>8</sup>



Clever-1 is expressed by blast cells and myeloid immune cells. Bexmarilimab activates the immune system and simultaneously may reduce the fitness of myeloid blasts via impairing their energy production

<sup>1)</sup> Hollmén et al. (2020) BJC. 123, 501-509 2) Salmi et al (2004) Blood. 104, 3849-3857 3) Shetty et al. (2011) J. Immunol. 186. 4147-4155 4) Palani et al. (2016) Eur. J. Immunol. 41 2052-2063. 5) Viitala et al. (2019) Clin. Canc. Res. 25 3289-3303 6) Kwon et al., (2019) Head Neck 41 2058-2064 7) Yin et al., (2020) Int. J. Cancer. 146. 1396-1408 8) Lin et al (2019) Mol. Thera. Nuc. Acids. 18, 476-484.

# Clever-1 is highly expressed by malignant cells in many hard-to-treat blood cancers



Source: 1) HEMAP dataset: Microarray data of 9,544 samples (Pölönen et al. Cancer Research 2019) http://hemap.uta.fi Clin Lymphoma Myeloma Leuk. 2013 Dec;13(6):711-5. doi: 10.1016/j.clml.2013.07.007. Epub 2013 Sep 17.

#### High expression of Clever-1 especially in MDS & AML

Clever-1 (*STAB1*) expression in primary samples from different hematological malignancies and normal myeloid cells

- RED Clever-1 high
- BLUE Clever-1 low

## Efficacy in r/r MDS Phase I/II BEXMAB Study - Bexmarilimab + Azacitidine

## Patient population and safety

Bex + Aza is well tolerated

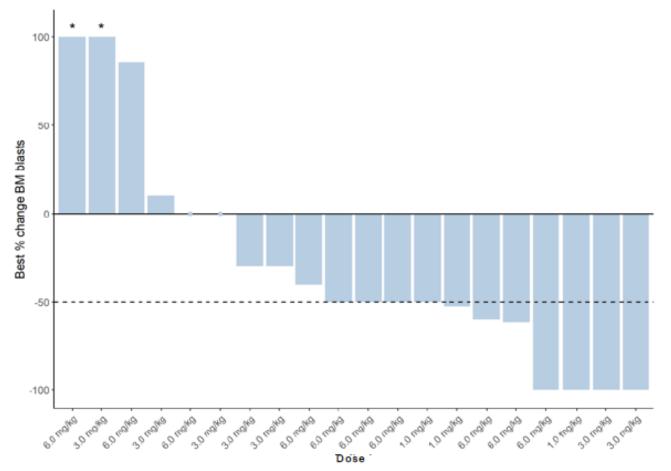
Patient Baseline Characteristics			r/r MDS, n (%)
Age (years); median (range)			72.5 (52-84)
ECOG PS		0	7 (35)
		1	13 (65)
IPSS-R	Intermed	iate (>3 - ≤4.5 points)	2 (10)
	Н	igh (> 4.5 - ≤6 points)	8 (40)
		Very high (> 6 points)	10 (50)
Mutations		TP53	9 (45)
		RUNX	4 (20)
N and type of previous therapy lines 1 2		1	10 (50)
		7 (35)	
≥3 Venetoclax + HMA			3 (15)
			8 (40)
	Ir	mmunotherapy + HMA	3 (15)

	Event count n	Subject count n (%*)
TEAEs, total	184	19 (95)
Grade ≥3	58	14 (70)
BEX-related AEs, total	25	7 (35)
Grade ≥3	0	0

\*% of r/r MDS patients, n=20

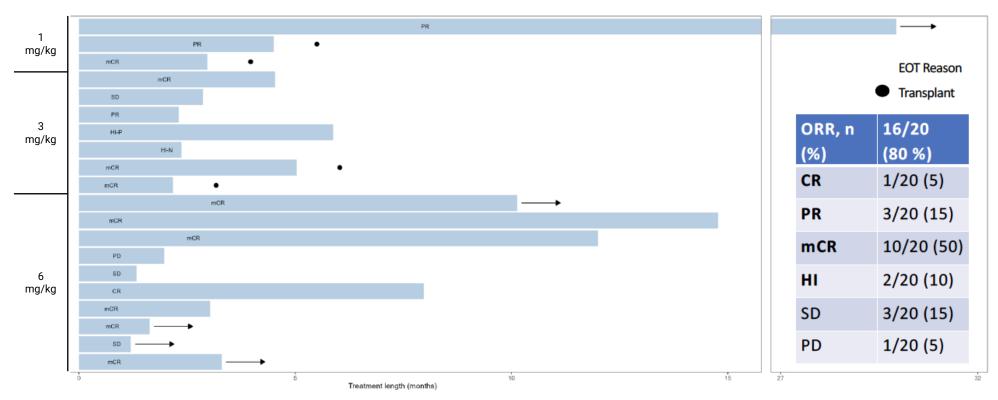
Two immune-related AEs, of which one was a BEX-related serious adverse event (Gr2 febrile neutrophilic dermatosis)

#### Phase 2 Efficacy in r/r MDS ≥50% Reduction of BM Blasts in 55% of r/r MDS patients



Waterfall plot showing best change in BM blast% vs. baseline. >5% BM lasts at baseline in 12/20 patients. \*actual change 250% (left) and 107% (right)

## Objective Response in 80% of r/r MDS Patients



Swimmer plot showing best response to BEX + AZA (IWG2018 criteria) and treatment duration in r/r MDS patients

- Remission (CR/PR/mCR) achieved in 14/20 (70%) patients
- mTP53: ORR 56% (5/9 patients)
- Ven + HMA pre-treated: ORR 63% (5/8 patients all CR/mCR)
- Transplant as end-of-treatment reason in 4/20 (20%) patients
- Current median overall survival estimate 13.4 months

# HRMDS Market Dynamics & Competitive Landscape

## The market opportunity in r/r MDS

MDS represents a significant growing market with an un-tapped area especially in r/r MDS

#### Estimated worldwide indication sales by year (USDbn)<sup>1)</sup> 180-510k MDS Patients in the US & EU<sup>3)</sup> 50% 50% 4.5 As a new, well tolerated effective Low-risk MDS **High-risk MDS** treatment, bexmarilimab has the opportunity to take a large share of the market 85% 15% 30-40% progress to Not eligible for High-risk MDS<sup>4)</sup> intensive therapy No transplant 1,4 **HMA** candidate 50% do not respond<sup>5)</sup> 5% 80% relapse in 1-2 years<sup>5)</sup> Alternatives after HMA failure No suitable HSCT include: another HMA, chemo, hydroxyurea, IDHdonor inhibitor (5%), clinical trial 2028 2023

#### MDS market growth

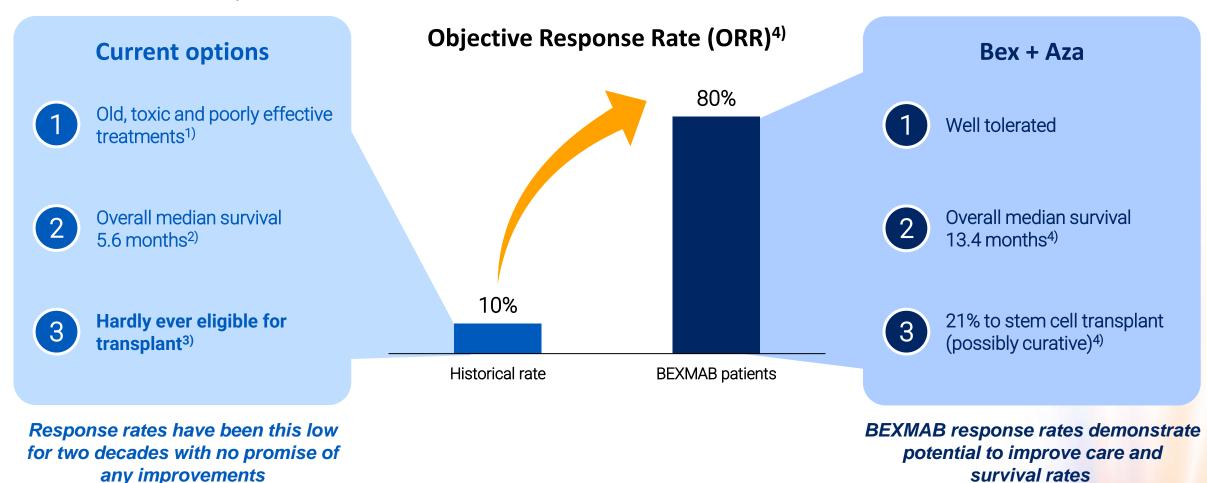
r/r MDS patient journey<sup>2)</sup>

#### Note: HSCT: Hematopoietic stem-cell transplantation

Source: 1) Evaluate Pharma 2024 Sales by indication 2) National Comprehensive Cancer Network 2024 3) Rollison et al. 2008 Epidemiology of myelodysplastic syndromes and chronic myeloproliferative disorders in the United States, 2001-2004, using data from the NAACCR and SEER programs; Bejar & Steensma 2014 Recent developments in myelodysplastic syndromes 4) Jain et al. 2024 Patterns of lower risk myelodysplastic syndrome progression: factors predicting progression to high-risk myelodysplastic syndrome and acute myeloid leukemia 5) Awada et al. 2023 What's Next after Hypomethylating Agents Failure in Myeloid Neoplasms? A Rational Approach

## **Current Phase 2 Results with Bexmarilimab**

Bexmarilimab has proven it can overcome treatment resistance



Source: 1) Fenaux et al. 2021 Myelodysplastic syndromes: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up 2) Prebet et al. 2011 Outcome of high-risk myelodysplastic syndrome after azacitidine treatment failure 3) Awada et al. 2023 What's Next after Hypomethylating Agents Failure in Myeloid Neoplasms? A Rational Approach 4) Faron press release titled "Faron Reports Initial Positive Phase 2 Read-out in HMA-resistant MDS" (2024)

### Market Dynamics and Competitive Landscape in MDS

Risk/benefit ratio is outstanding with Bex, and key to approval and commercial up-take

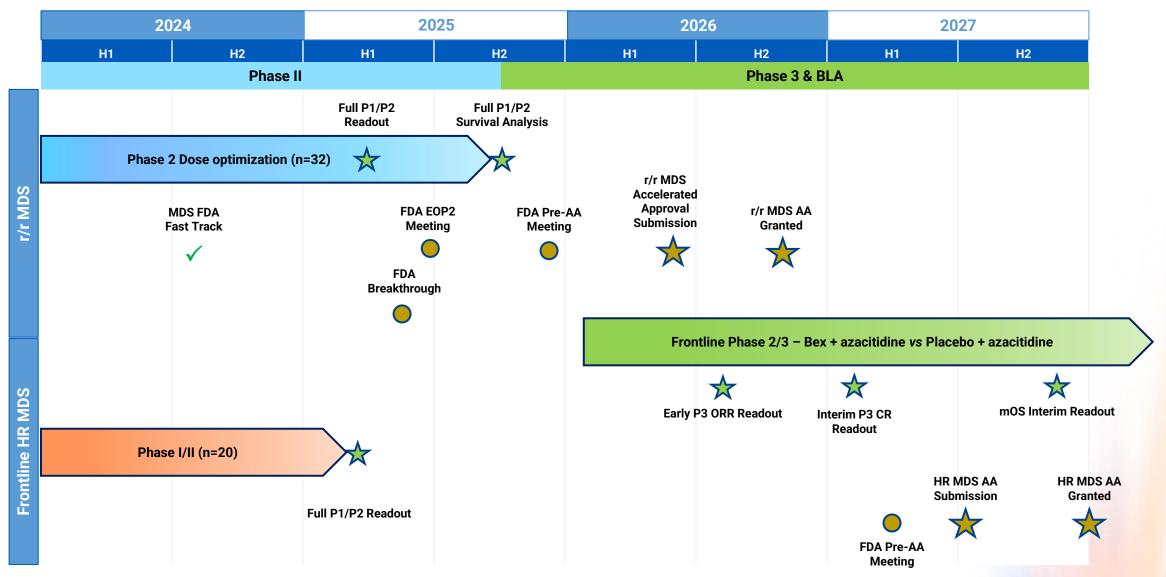
- Vibecotamab (CD3-CD123 T-cell engager) in r/r MDS (ASH 2024 abstract #1007):
  - N = 16 r/r MDS patients treated: ORR 56%, 0% CR+PR, mCR with limited hematological improvement (31%), mOS 10.3 months, TRAE 68% (IIT running in MD Anderson, discontinued by Novartis/Xencor)

#### • Venetoclax + Aza:

- Ven + Aza in r/r MDS (ASH 2024 abstract #3209): N = 32, ORR 48% (mainly mCR), 12% to HSCT, mOS 7 months
- The VERONA trial (Ven + Aza in 1<sup>st</sup> line HR MDS) read out has been postponed. The primary endpoint has been changed from CR to mOS. In Phase 2 CR rate was 30%, no clear survival benefit against historical data
- Over 90% of patients on Ven + Aza have TRAE, which are often severe and may even lead to death

## Development Plan in HR MDS and Outlook into the Future

## **Development Plan for HR MDS per FDA Guidance**



#### 16 FEB-2025

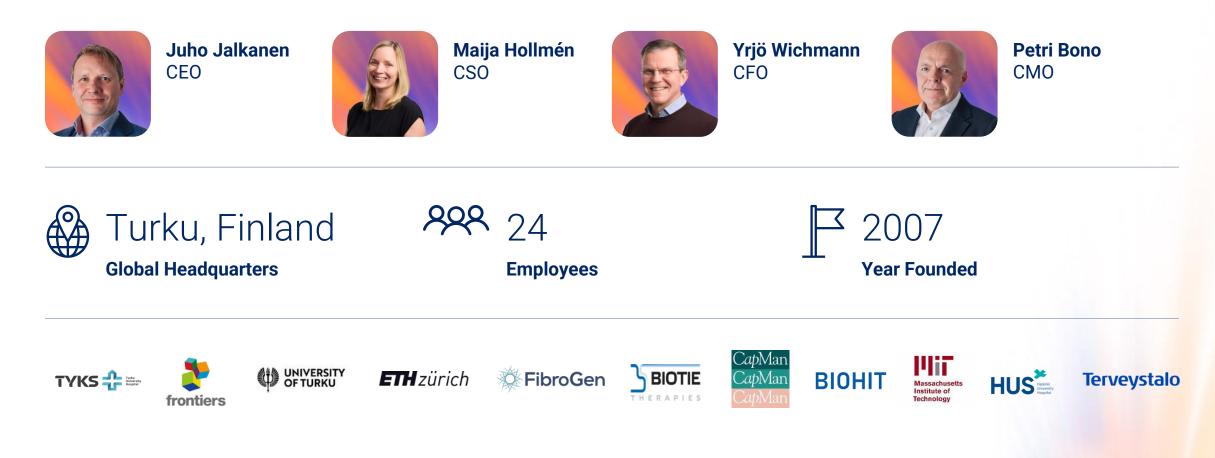
## Outlook into 2025

Full Phase 2 readouts, regulatory interactions, and combo data with anti-PD-1

- > Jan 2025 Phase 2 enrollment completed
- > End of Q1 2025 full Phase 2 response rate readout (r/r)
- > End of Q2 2025 FDA EOP2 meeting and Breakthrough Designation possibility
- > End of Q3 2025 Phase 2 duration of response and survival data (r/r MDS)
- > Q4 2025 Regulatory feedback on accelerated approval
- > Q4 2025 First combination data with anti-PD1 (Phase 2 BLAZE Trial)

## Management

World leading science and oncology drug development from Finland



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Further depth and experience

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**Toni Choueiri, MD, FASCO** Professor Harvard, USA



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**Mika Kontro, MD, PhD** Adjunct Professor HUS, CCC



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# Thank You