

# ACTIVATE YOUR BODY TO DEACTIVATE CANCER

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24

Employees



2007

Year Founded



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Further depth and experience

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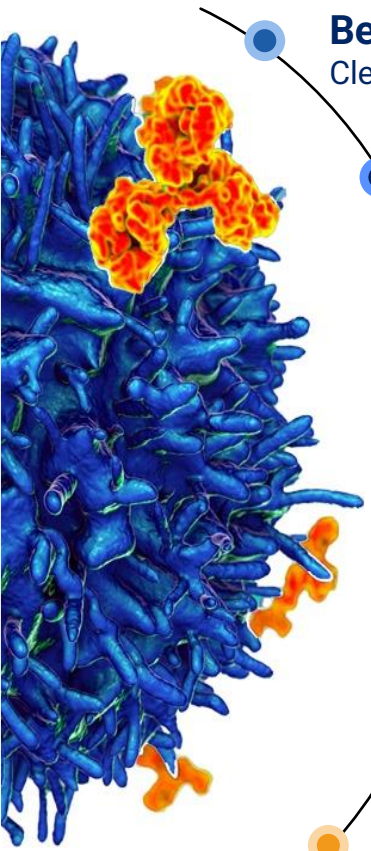


**Cristophe Massard, MD, PhD**

Professor  
Gustave Roussy CCC, Paris



# Harnessing the Power of Macrophages to Conquer Treatment Resistance



**Bexmarilimab** is a first-in-class anti-CLEVER-1 antibody

Clever-1 is a master immunosuppressive receptor on myeloid cells and leukemic blasts, highly expressed in treatment resistant AML & MDS

**Bexmarilimab is currently in Phase 2** for the treatment of last line higher-risk myelodysplastic syndrome (r/r MDS)

Currently there are very limited treatment options for patients with r/r MDS

**r/r MDS is one of the deadliest of all cancers**

Response rates to salvage treatments vary from 0 – 20% and survival is only 5.6 months, historically

**Exceptional Phase 2 interim data for r/r MDS reported at ASH 2024**

An increase in overall median survival from 5.6 months to 13.4 months and an increase in ORR from 10% to 80%  
Topline Phase 2 results coming out in April 2025

**Positive regulatory interactions**

FDA Fast Track Designation for r/r MDS with accelerated approval possibility according to project FrontRunner  
MHRA Innovation Passport (ILAP), UK equivalent to Fast Track Designation  
FDA & EMA Orphan Drug status for MDS

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

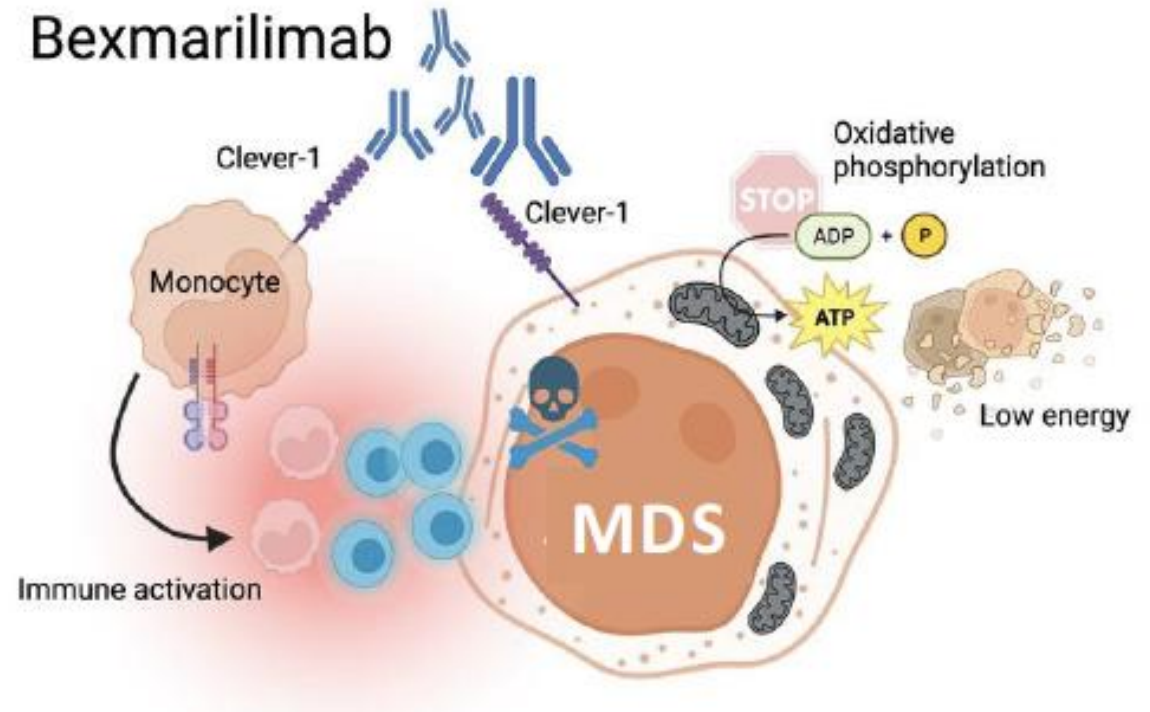
Faron is also investigating Bex for advanced solid tumors in combination with chemo and PD-1s  
20-30% of all cancers are Clever-1 positive

# An Overview of the Target

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

### Clever-1

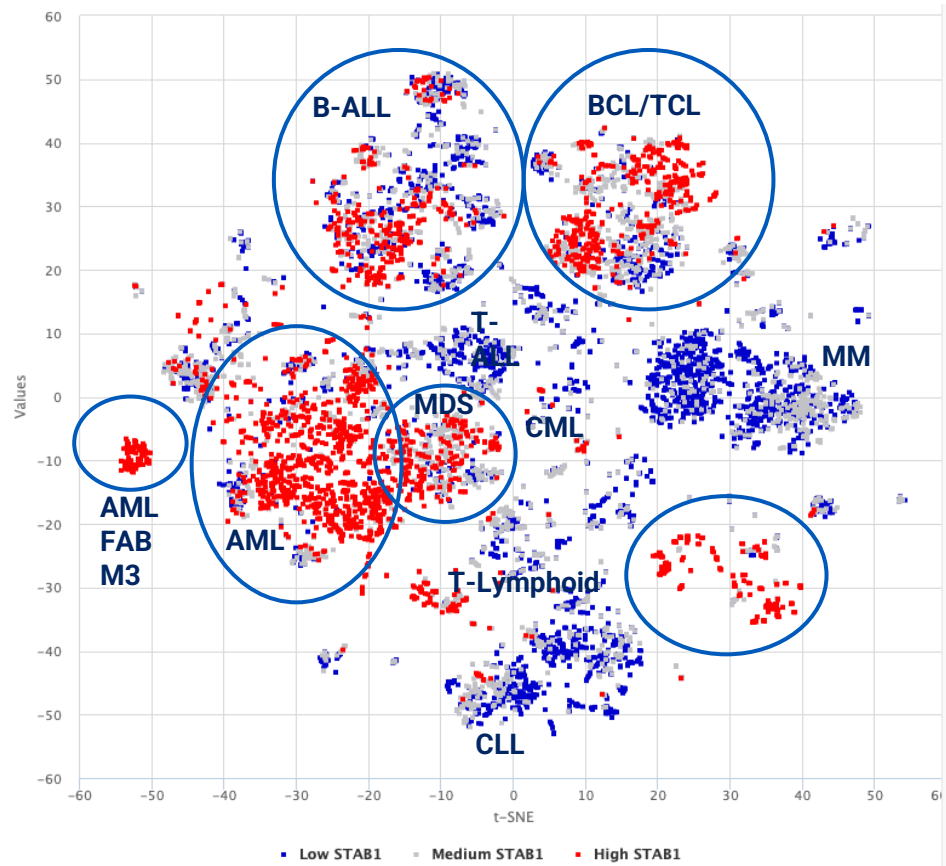
- A scavenger receptor expressed by leukemic myeloid cells and immunosuppressive macrophage populations<sup>1</sup>
- Involved in receptor-mediated endocytosis and recycling of altered and normal self-components
- Regulates leukocyte trafficking<sup>2,3</sup>, inhibits T cell activation<sup>4</sup> and 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

1) 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



## 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

Source: 1) HEMAP dataset: Microarray data of 9,544 samples (Pölonen 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.

# Efficacy in r/r MDS

Phase I/II BEXMAB Study - Bexmarilimab + Azacitidine



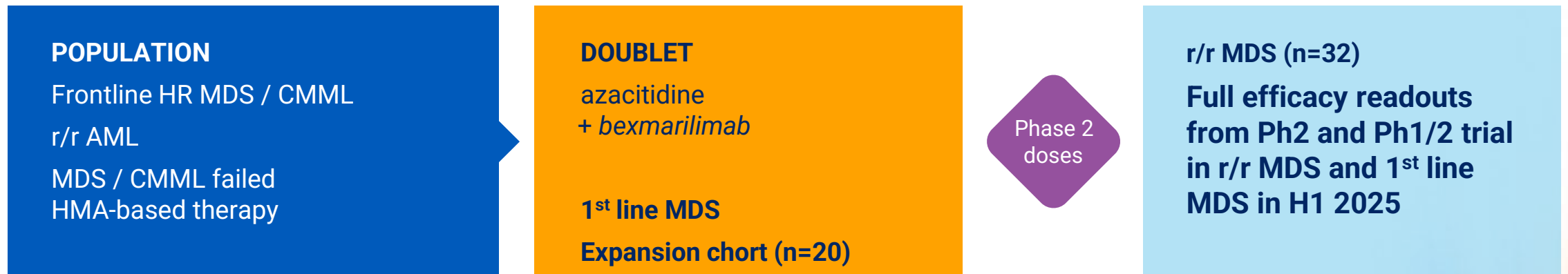
# Study design: Phase I/II Study Evaluating *Bexmarilimab* with Standard of Care

## Dose Finding (Phase I)

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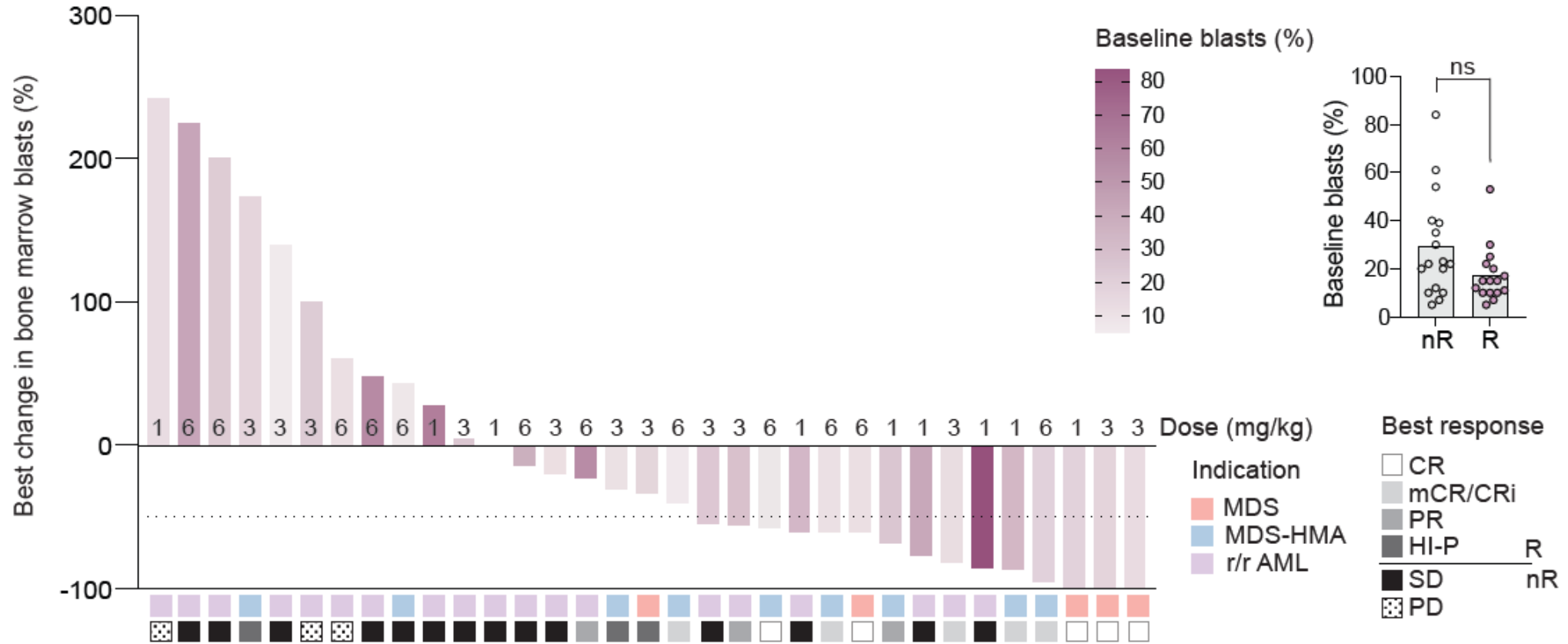
## Efficacy Evaluation (Phase II)

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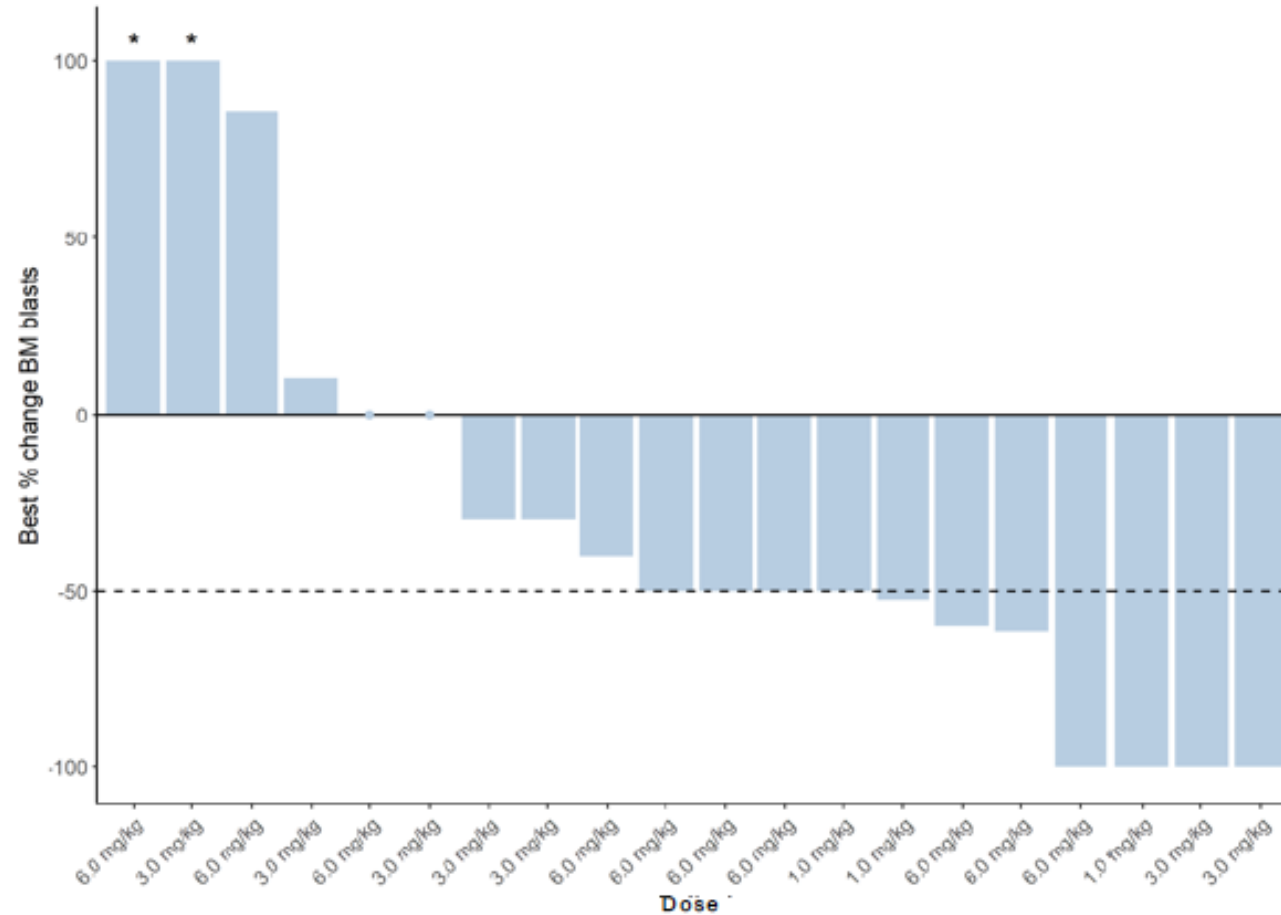
Trial sites: 4 sites in US (MD Anderson, Yale, City of Hope and UNC), 2 UK sites and 4 Finnish sites

# Phase 1 Efficacy of Bex + Aza in Patients with MDS or r/r AML (n=33)



# Phase 2 Efficacy in r/r MDS

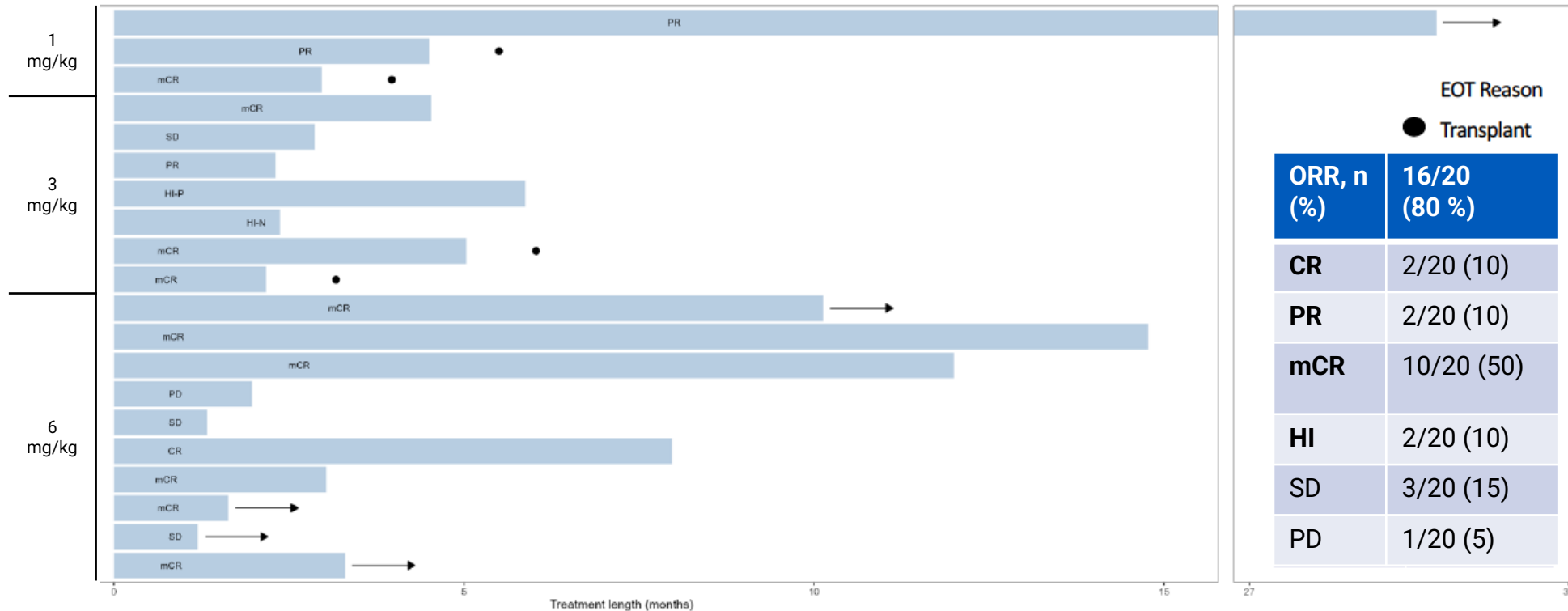
Strong and long-lasting results with median time on treatment 8 months



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



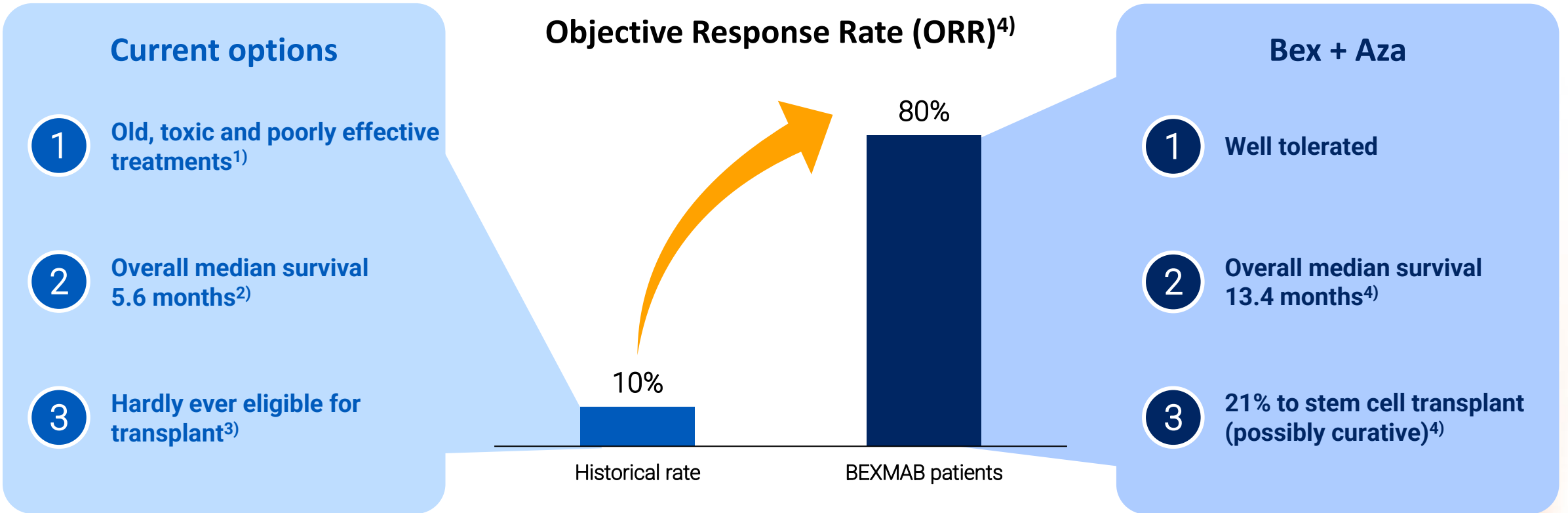
Swimmer plot showing best response to BEX + AZA (IWG2018 criteria) and treatment duration in r/r MDS patients

- 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**



# Phase II results with Bexmarilimab

*Bexmarilimab* has proven it can overcome treatment resistance



***Response rates have been this low for two decades with no promise of any improvements***

***BEXMAB response rates demonstrate potential to improve care and survival rates***

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)

# MDS Safety Data

Phase I/II BEXMAB Study & Overall Exposure in 274 Patients

# 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	Intermediate (>3 - ≤4.5 points)	2 (10)
	High (> 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	10 (50)
	2	7 (35)
	≥3	3 (15)
	Venetoclax + HMA	8 (40)
	Immunotherapy + 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

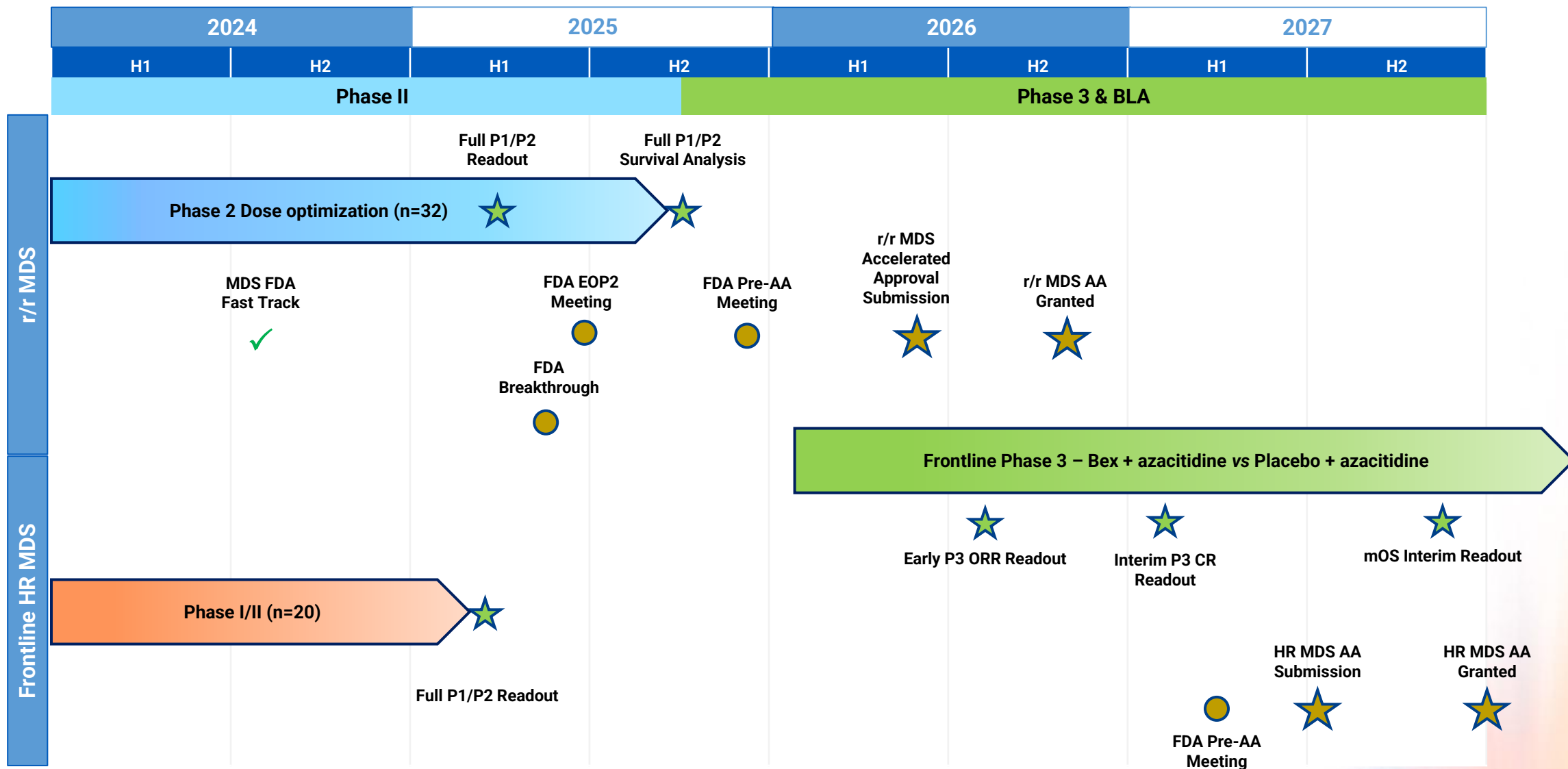
Two immune-related AEs, of which one was a BEX-related serious adverse event (Gr2 febrile neutrophilic dermatosis)

The background of the slide features a microscopic view of cells. Several large, spherical, blue-colored cells with a textured, spiky surface are scattered across the frame. Interspersed among these are smaller, more irregularly shaped cells with a yellow and red color scheme, possibly representing different cell types or stages of development. The overall lighting is dim, with a dark blue background.

# Development Plan in HR MDS and Outlook into the Future



# Development Plan for HR MDS per FDA Guidance



# Outlook into 2025

Phase 2 readouts, regulatory interactions, and business transactions

## April

Top line Phase 2 response rate and safety readout

## May/June

Detailed data presented at upcoming major congresses (ASCO & EHA)

## End of Q2

FDA EOP2 meeting and Breakthrough Designation possibility

## End of Q3

Phase 2 duration of response and survival data

## Q4 2025

Regulatory feedback on accelerated approval possibility

In addition: First solid tumor trial patients treated in H2/2025

The background of the slide is a dark blue, semi-transparent image of a microscopic scene. It features several large, spherical, blue, textured structures that resemble virus particles or cell clusters. Interspersed among these are smaller, more irregular, yellow and orange structures, possibly representing other biological components or cells. The overall aesthetic is scientific and high-tech.

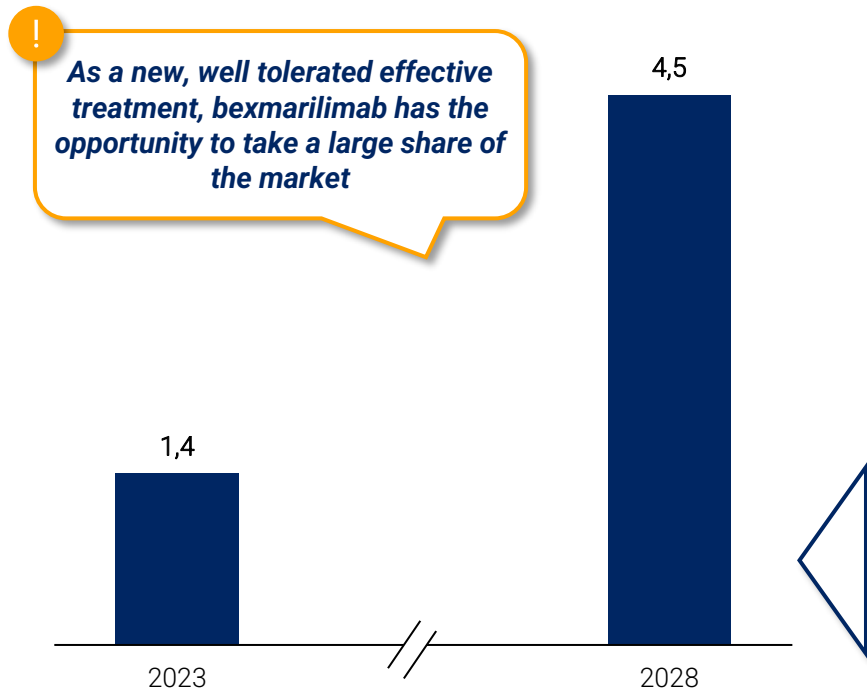
# Competitive landscape in HR MDS

# The market opportunity in r/r MDS

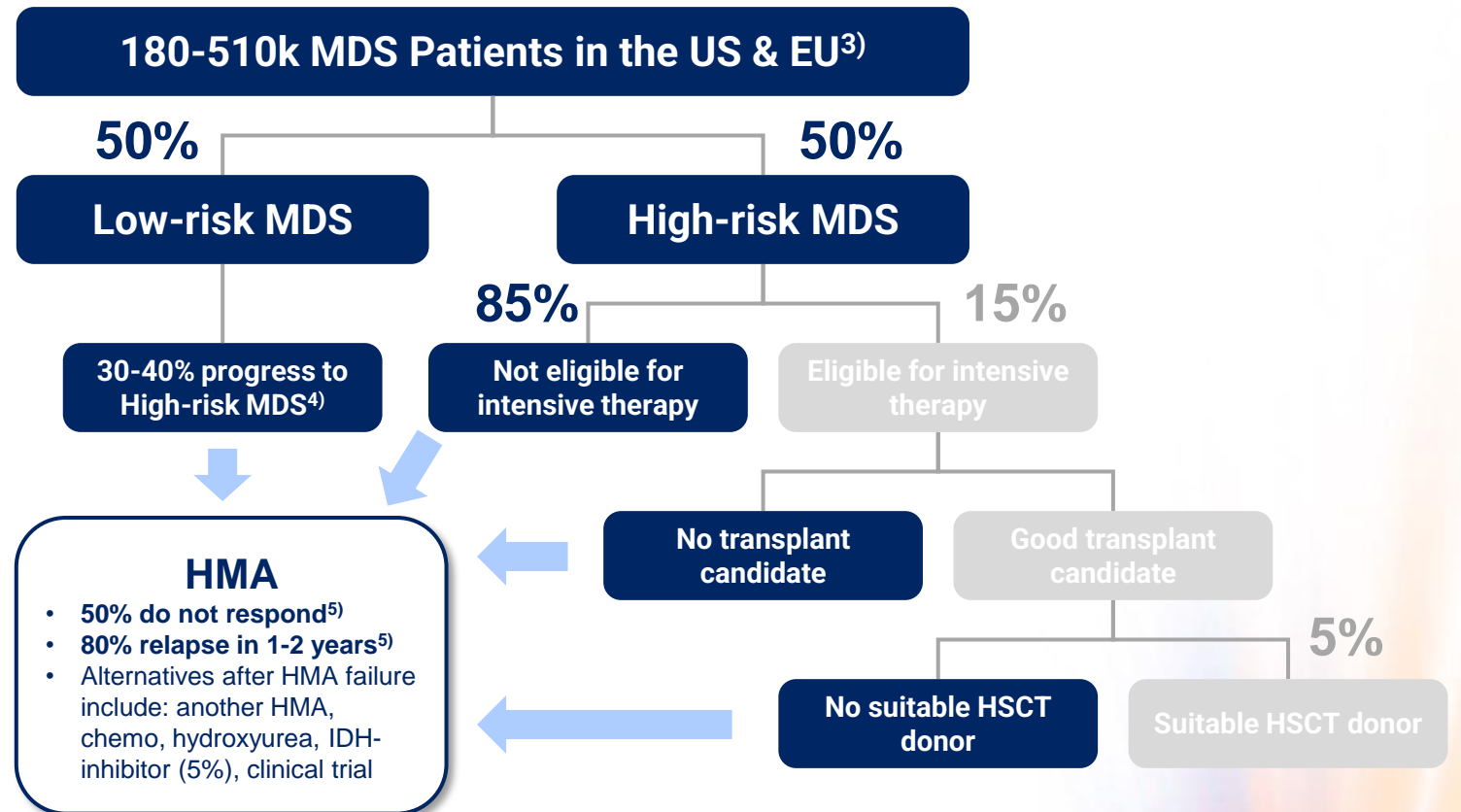
HR MDS represents a significant growing market with an un-tapped area especially in r/r MDS

## MDS market growth

Estimated worldwide indication sales by year (USDbn)<sup>1)</sup>



## 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*



# 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
- **Rytelo (imetelstat) Phase 3 results in treatment resistant LR MDS:**
  - No remissions, RBC transfusion independence 40% vs. 15% compared to placebo
  - Myelosuppressive leading to drops in blood counts

# Acceptable pricing in the US



Market research indicates that *bexmarilimab* is likely to become a highly prescribed and priced drug for the treatment of HR MDS. Priced similarly to Rytelo is not likely to add restrictions. However some more plans might look to reduce the price to a lower level through rebates. Prices \$18k – \$25k per month are realistic.

R/R MDS	US #1	US #2	US #3	US #4
\$10,000/month	○	○	○	○
\$14,000/month	○	○	○	○
\$18,000/month	○	○	○	○
\$22,000/month	○	○	○	○
\$25,000/month	○	○	○	○
\$20,000/month	○	○	○	○
\$30,000/month	○	○	○	○

Rytelo

HR MDS 1 <sup>st</sup> line	US #1	US #2	US #3	US #4
\$10,000/month	○	○	○	○
\$14,000/month	○	○	○	○
\$18,000/month	○	○	○	○
\$22,000/month	○	○	○	○
\$25,000/month	○	○	○	○
\$20,000/month	○	○	○	○
\$30,000/month	○	○	○	○

Rytelo

Legend:



Likely to cover



Cover with higher restrictions



Too expensive, unlikely to cover

NB: US payers #2 and #3 confirmed that their health plans do not impose pricing-based restrictions on drugs like *bexmarilimab*. Despite considering Rytelo's price high, they have covered it without formal restrictions. Therefore, we recommend using Rytelo as a price benchmark.


# Differentiation of Bex in Macrophage Reprogramming:

Superior performance in removing immunosuppression and igniting T-, NK-, and B-cell responses


## Scavenger receptors (namely CD163, CD206, MARCO)

 Clever-1 is the biggest scavenger receptor with multiple functions and natural ligands. In our pre-clinical investigations it is superior to other scavenger receptors that are more specific to a certain ligand/function

## LILRBs

 Seem to have similar biology to Clever-1 (present both in the placenta and immunosuppressive tumors), but to date Bex has shown superior clinical results in AML & MDS, as well as stronger modulation of the TME in solid tumors

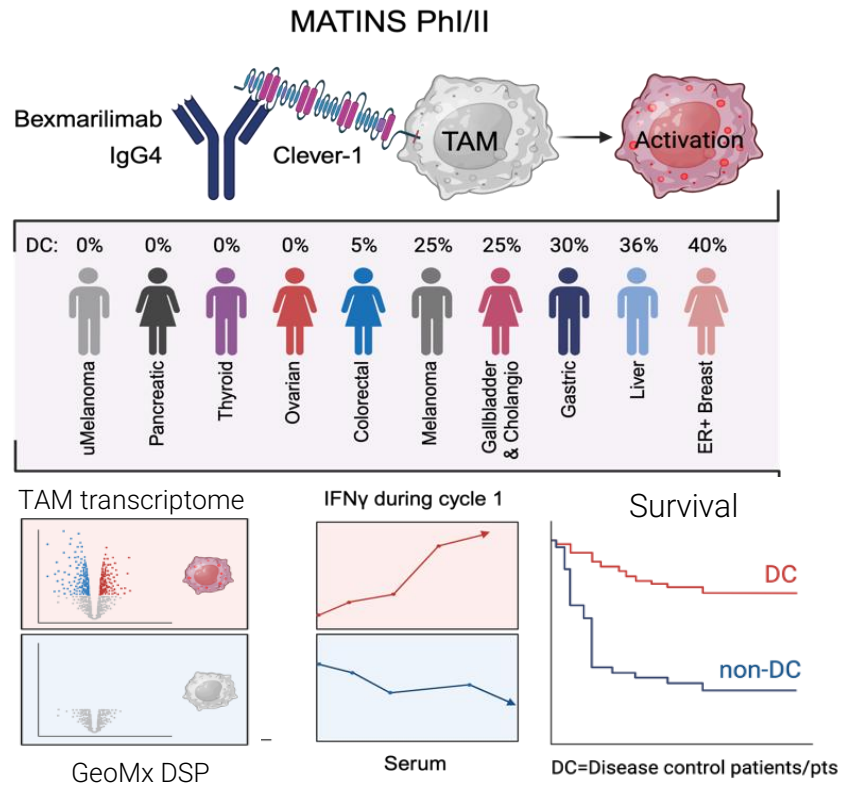
## CD47-SIRPa & "don't eat me" (DEM) pathways

 Very poor clinical data as single agents in solid tumors, widely expressed and poor tox profile. Conceptually the MoA is very different to Bex, as targeting the DEM pathway will allow macrophages to eat what they encounter, while Bex will allow macrophages to present what they eat. Combining these MoA could be very synergistics

# *Bexmarilimab* in solid tumors

# Proof of Principle of Modulating the Tumor Microenvironment (TME)

## Phase 1/2 First-in-Human MATINS Trial



## Highlights

- 216 patients treated across 10 different cancer types
- Targeting Clever-1 with bex is well tolerated, RP2D 1mg/kg Q3W supported by the FDA
- Bex converts intratumoral macrophages to support adaptive immune responses and IFN $\gamma$  signaling
- Bex monotherapy modified the TME, which led to increased survival in late-stage cancer patients
- Low baseline immune activation associates with clinical benefit from Bex

Source: 1) MoA: Mechanism of Action, TME: Tumor Microenvironment

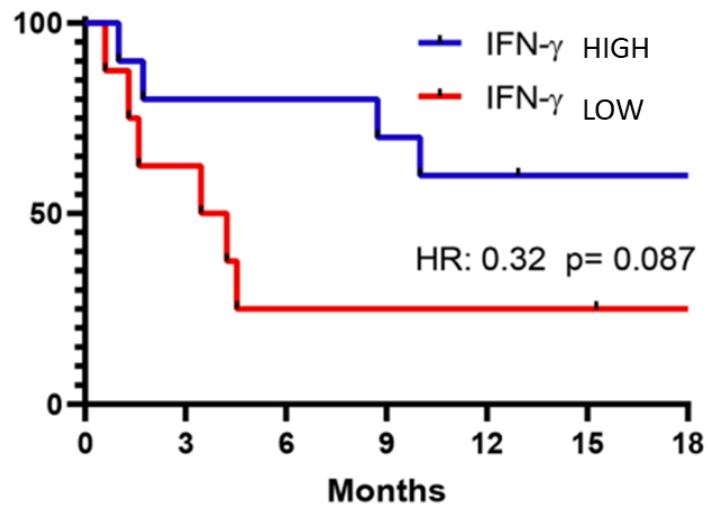
Source: 2) Rannikko et al. (2023) Cell Reports Medicine, 4, 101307, available in open access. See Faron release on December 7th, 2023



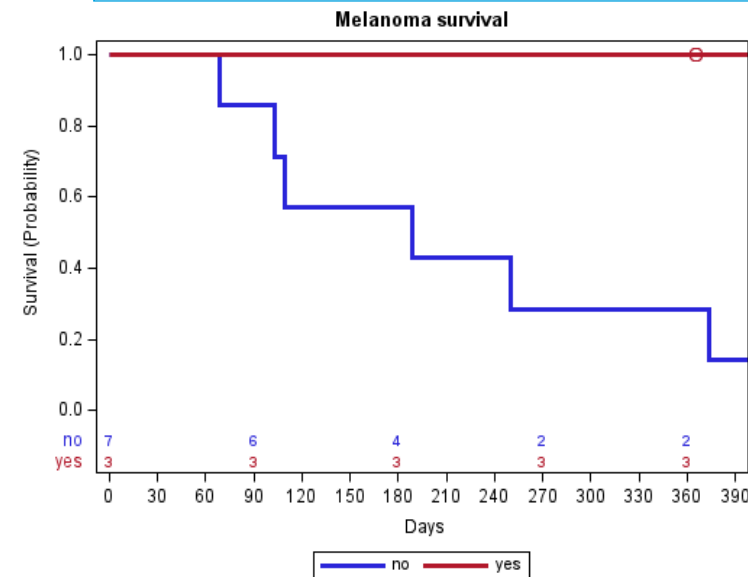
# Bexmarilimab – a drug for cold (IFN $\gamma$ low) tumors

As single agents *bexmarilimab* and anti-PD-1s benefit opposite melanoma populations

Anti-PD1 treated melanoma patients according to IFN gamma status<sup>1,2</sup>



Bex treated melanoma patients according to IFN gamma status<sup>3</sup>



Faron's *bexmarilimab* aims to tackle the immunosuppressive microenvironment characterized by low IFN- $\gamma$ , inactive T-Cells and a high amount of Clever-1 positive, immunosuppressive tumor associated macrophages.

Source: 1) 1) Giunta et al. Scientific Reports 2020. 2) Ayers et al. J Clin Invest. 2017 3) MATINS Phase I/II first-in-human trial with *bexmarilimab* in advanced solid tumors

# Solid Tumour Pipeline

Treatment	Indication(s)	Phase of Development				Anticipated Key Milestones
		Preclinical	Phase 1	Phase 2	Phase 3	
<b>Single-Agent Bexmarilimab</b>	Advanced solid tumors <b>FARON SPONSORED</b>	MATINS (First in Human, single agent)				<ul style="list-style-type: none"> <li>Completed</li> </ul>
<b>Bexmarilimab + PD-1</b>	PD-1 Blockade Basket trial in Solid Tumors <b>FARON SPONSORED</b>	MATINS-02				<ul style="list-style-type: none"> <li>First-patient-in expected in Q1 '26</li> </ul>
	PD-1 resistant NSCLC and Melanoma <b>INVESTIGATOR INITIATED</b>	BLAZE				<ul style="list-style-type: none"> <li>First-patient-in expected in Q3 '25</li> </ul>
	Soft Tissue Sarcomas <b>INVESTIGATOR INITIATED</b>	BEXAR				<ul style="list-style-type: none"> <li>First patient in expected in Q4'25</li> </ul>
<b>TBC</b>	Lymphomas (DLBCL and TCL) <b>FARON SPONSORED</b>	MATINS-03				<ul style="list-style-type: none"> <li>Preclinical expected to complete Q2'25</li> </ul>



Thank You