A CLEVER Approach to
**Fight Cancer**

# Faron Pharmaceuticals

Dr. Markku Jalkanen, CEO

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London AIM: FARN
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# Investment Highlights

## A CLEVER Approach to Fight Cancer via Re-programming Macrophages and Myeloid Cells

Bexmarilimab (Bex) is a humanized anti-Clever-1 antibody, which by a novel mode of action primes the immune system to attack tumors

Bex is potentially applicable to a wide range of hematologic diseases and solid tumors in combination with traditional therapies, or as maintenance therapy

Bex has shown clinical benefit as a single agent in ~200 patients with advanced solid tumors refractory to PD-1 blockade (MATINS study) and 33 difficult-to-treat patients with myeloid malignancies (BEXMAB study)

Significant ORR achieved in patients with HR-MDS (5/5) and HMA-failed MDS (5/5), including patients with TP53 mutation (ASH 2023)
Phase 2 focuses on MDS patients who have failed prior HMA therapy, with readouts in 2Q and 4Q 2024

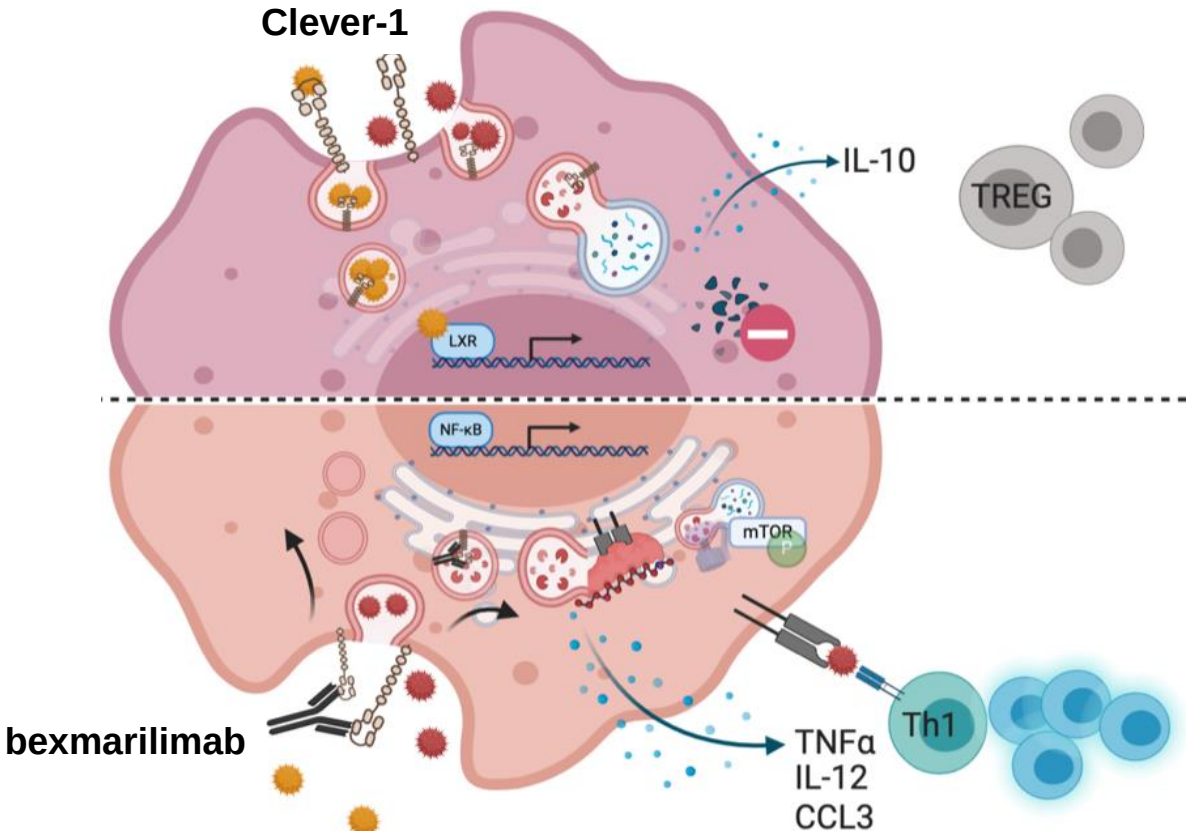
MDS alone represents a large and growing indication with projected sales in 8 major markets of over $2 billion by 2028*
Patent protection to 2037

*Global Data (2020)

ORR: Overall Response Rate, TAM: Total Addressable Market

# Bex: Proven anti-Clever-1 mechanism of action

## An innovative approach to hematological malignancies and solid tumors




**Clever-1⁺ macrophages**
"Do not show me"

**After Clever-1 blocking**
"Show me"

**Clever-1 is an immunosuppressive receptor on macrophages that helps cancer evade the immune system.**
**Bex blocks Clever-1 and primes immune system to attack tumors to enhance clinical benefit of concomitant therapies**



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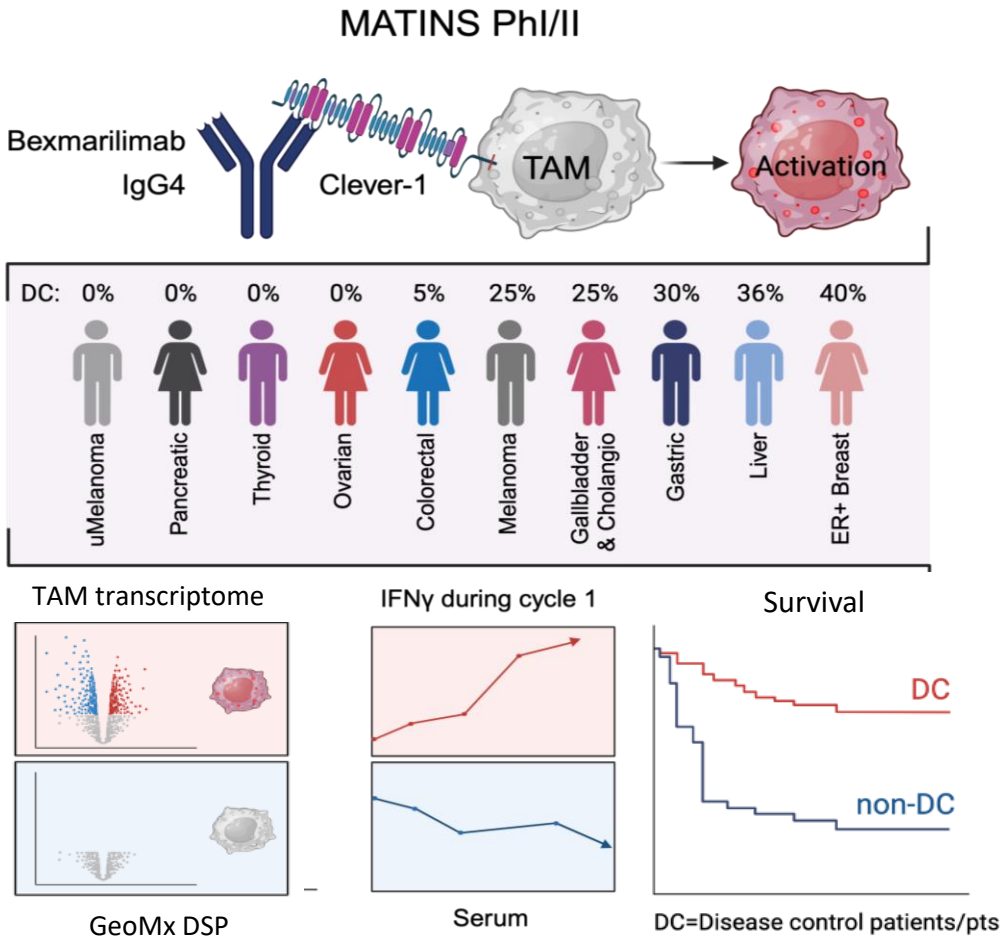
# Proof of Principle for Modulating Tumor Microenvironment (TME)

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




### Highlights

In the MATINS Phase 1/2 trial BEX as a single agent demonstrated proof of principle for anti-Clever- 1 in 10 different cancer types in ~200 patients

Targeting Clever-1 with bex is well tolerated

Bex converts intratumoral macrophages to support adaptive immune responses and IFNg signaling

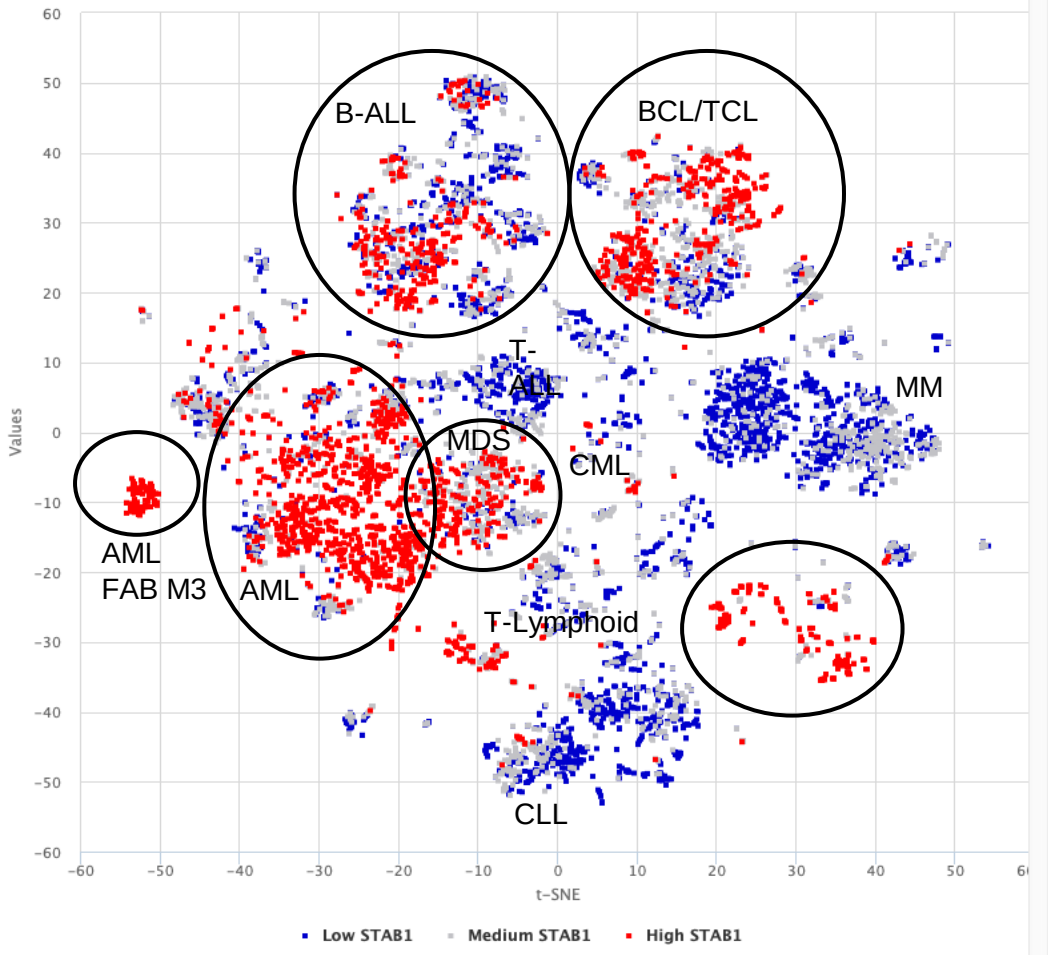
Bex monotherapy changed the TME, which led to increased survival in late-stage cancer patients

Low baseline immune activation associates with bex benefit

MoA: Mechanism of Action, TME: Tumor Microenvironment

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

# Clever-1 is highly expressed by malignant blast cells in AML and MDS



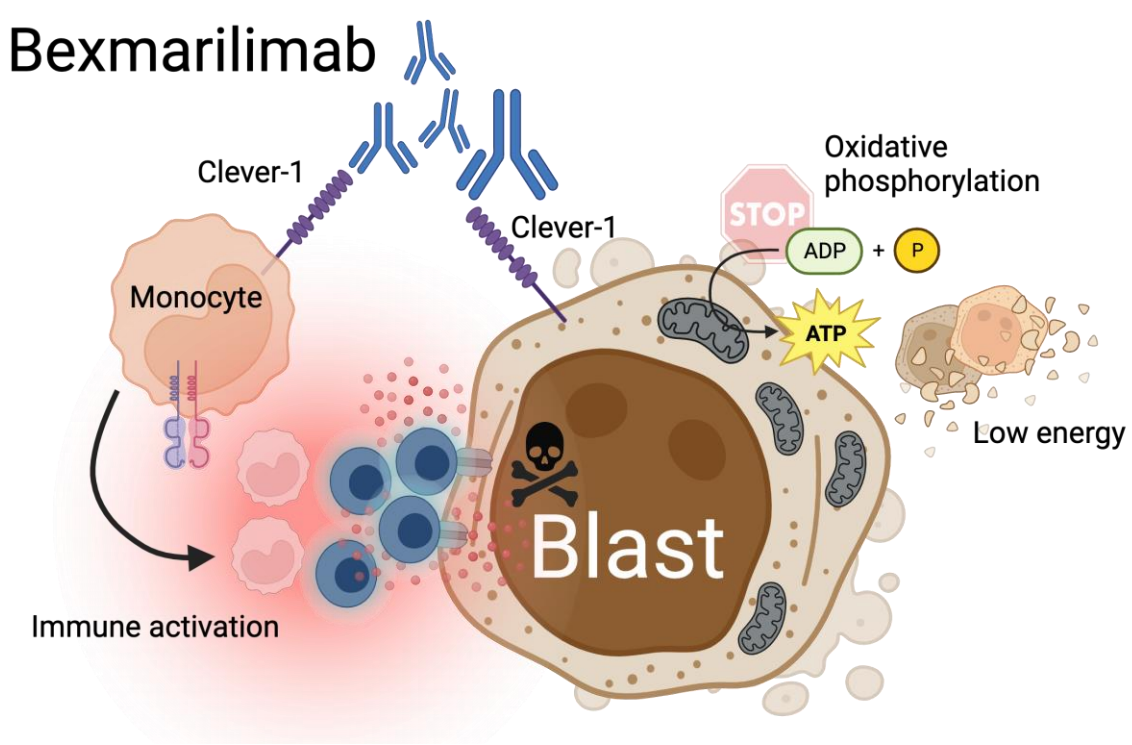

HEMAP dataset: Microarray data of 9,544 samples (Pölönen et al. Cancer Research 2019) http://hemap.uta.fi
MDS: myelodysplastic syndrome
Clin Lymphoma Myeloma Leuk. 2013 Dec;13(6):711-5. doi: 10.1016/j.clml.2013.07.007. Epub 2013 Sep 17.

**Patients with higher-risk MDS, in whom azacitidine (HMA-agent) treatment has failed, have a poor prognosis and low probability of response to salvage treatments**

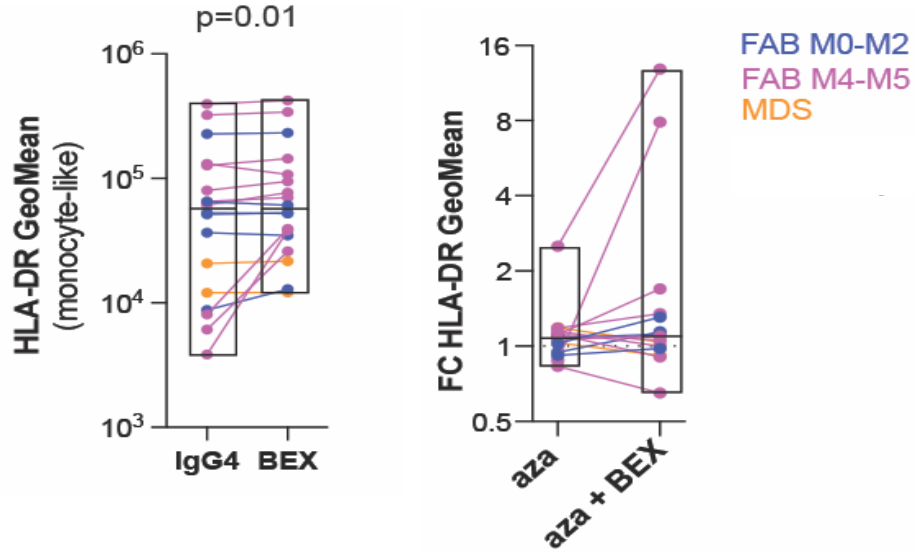
Clin Lymphoma Myeloma Leuk. 2013 Dec;13(6):711-5. doi: 10.1016/j.clml.2013.07.007. Epub 2013 Sep 17.

# Targeting Clever-1 in Myeloid Malignacies

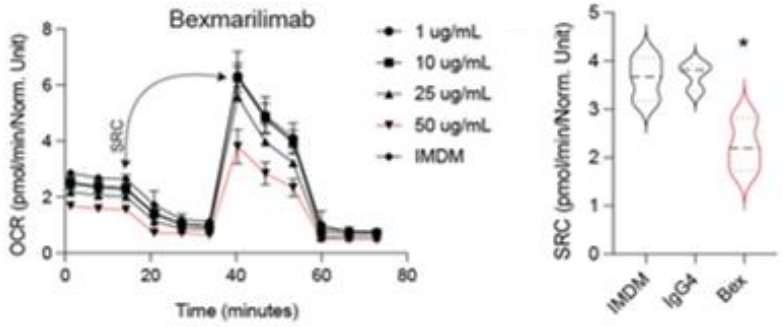
## PoC Bex in combination with SOC in hematological malignancies – HR MDS and r/r AML




In AML, Clever-1 is expressed by blast cells and adjacent myeloid immune cells. The antibody can activate the immune system in the bone marrow and simultaneously reduce the fitness of AML blasts through impairing cells' energy production.




Bexmarilimab increases HLA-DR expression by monocyte-like cells and improves azacytidine-induced HLA-DR in a subset od patient samples. Data from AML bone marrow ex vivo cultures (n = 18). Aakko et al., submitted.

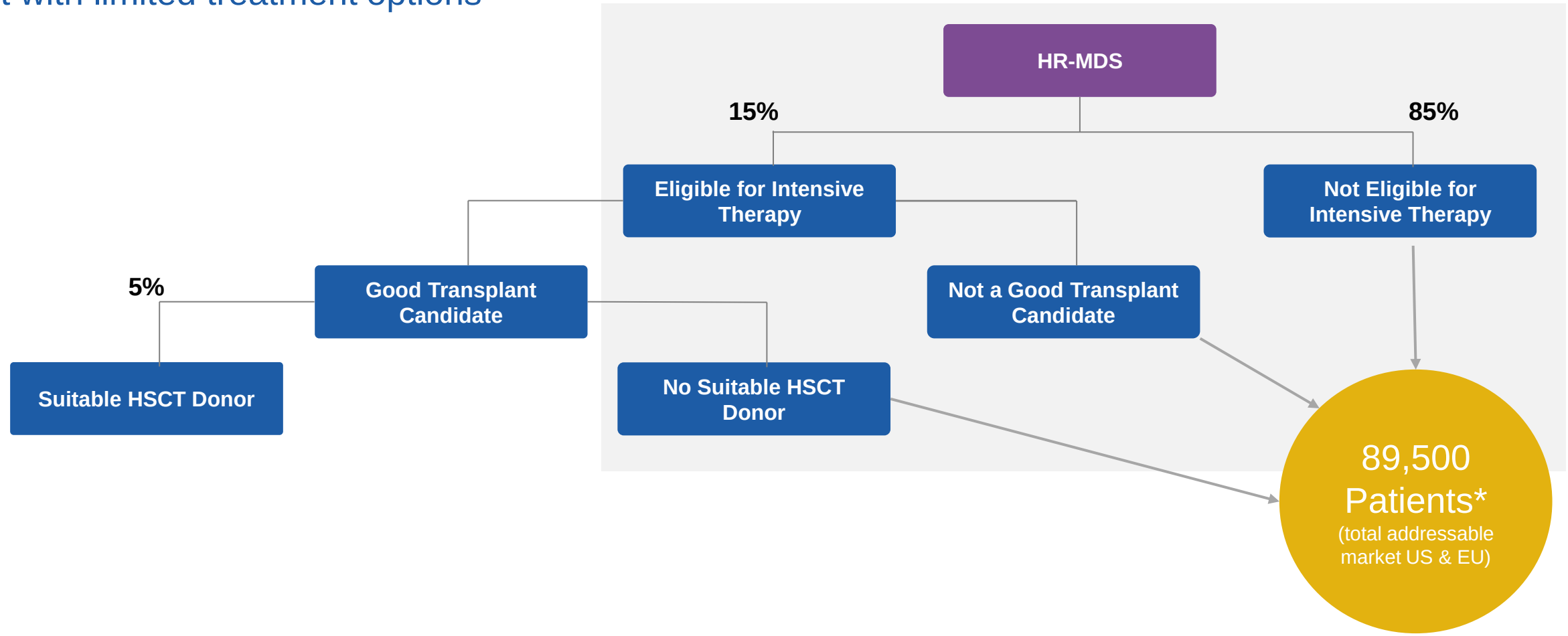



Seahorse Mito stress test kit was used for measuring mitochondrial function after 48h treatment on KG1 cells.

AML: Acute Myeloid Leukemia, HLA-DR: Human Leukocyte Antigen – DR isotype, aza: azacitidine
Ylitalo et al (2023) Presented AACR AML

# Higher-Risk MDS Patient Journey

## ”HMA or nothing” – significant unmet need with 85% of patients not eligible for intensive therapy and left with limited treatment options




*Source: GlobalData; adapted from Montalban-Bravo and Garcia-Manero, 2018, Steensma, 2018, NCCN, PharmaVentures market assessment
MDS: myelodysplastic syndrome, HSCT: Hematopoietic stem-cell transplantation

# BEXMAB Phase 1/2 Study Evaluating Bex with SoC in Myeloid Malignancies

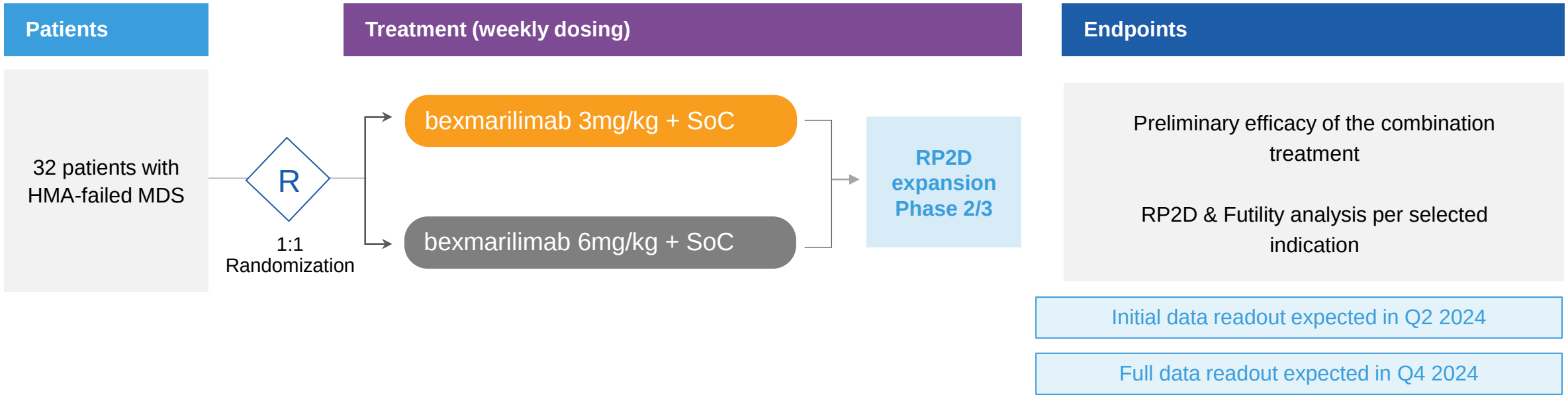
## Expect to dose patients in Phase 2 in January 2024

**Phase 1 Findings**

36 patients treated in doublet/triplet with 3 dose levels have been evaluated

- Highest immune activation, as observed in the accumulation of activated immune cells in patient bone marrow, was observed in both 3 mg/kg and 6mg/kg cohorts
- Significant overall response rate observed in HMA-failed (5 out of 5) and higher-risk MDS patients (5 out of 5)
- Both dose levels (3 mg/kg and 6mg/kg) have been safe and well tolerated to date

**Phase 2**




SoC: Standard of Care, MDS: myelodysplastic syndrome, RP2D: Recommended Phase 2 Dose

# Adding Bexmarilimab to SoC is Well Tolerated

## No DLTs have been reported and most AEs are of Grade 1/2

| | All (n=28) % | 1.0mg/kg (n=7) % | 3.0mg/kg (n=11) % | 6.0mg/kg (n=10) % |
|---|---|---|---|---|
| Any TRAE | 12 (43) | 3 (43) | 4 (36) | 5 (50) |
| Pyrexia | 3 (11) | 1 (14) | 0 | 2 (20) |
| Blood TSH increased | 2 (8) | 0 | 0 | 2 (20) |
| Constipation | 2 (8) | 2 (29) | 0 | 0 |
| Nausea | 2 (8) | 0 | 1 (9) | 1 (10) |
| Worsening of neutropenia | 2 (8) | 0 | 2 (18) | 0 |
| ALT increases | 1 (4) | 0 | 1 (9) | 0 |
| CLS (capillary leak syndrome) | 1 (4) | 0 | 1 (9) | 0 |
| HLH (hemophagocytic lymphohistocytosis) | 1 (4) | 0 | 1 (9) | 0 |
| Cryptic organizing pneumonia | 1 (4) | 0 | 0 | 1 (10) |
| Pain | 1 (4) | 0 | 0 | 1 (10) |
| Post-procedural bleeding | 1 (4) | 0 | 0 | 1 (10) |
| Rash | 1 (4) | 0 | 0 | 1 (10) |
| Vomiting | 1 (4) | 1 (14) | 0 | 0 |

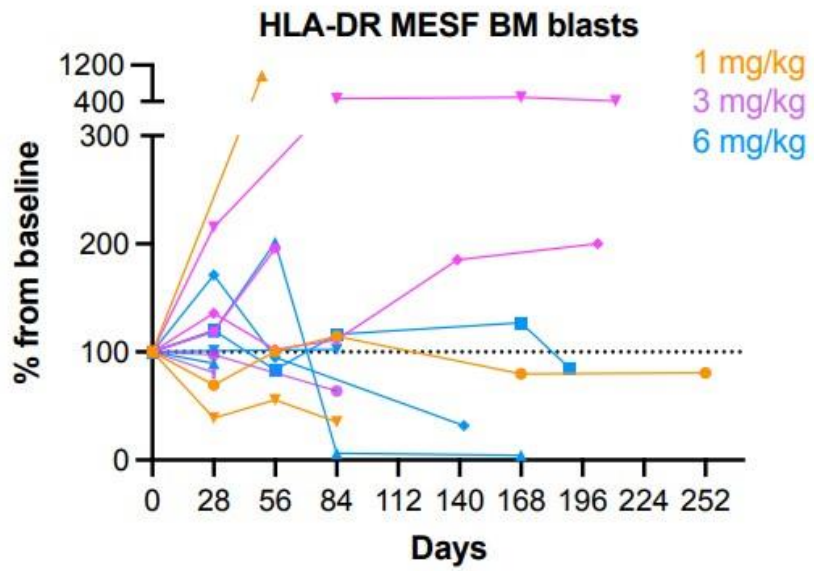
| | AEs n |
|---|---|
| **Any Grade** | 244 |
| ≥ Grade 3 | 81 |
| SAEs | 37 |
| **Related AEs** | |
| Any Grade | 24 |
| ≥ Grade 3 | 9 |

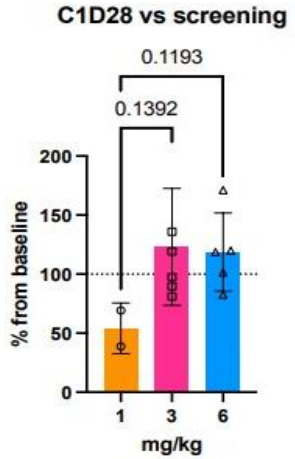
- No dose-limiting toxicities (DLT)
- SAEs related to BEX:
  - n=2 at 3mg/kg: Capillary leak syndrome (Gr 3); Hemophagocytic lymphohistiocytosis (Gr 5);
  - 6mg/kg Cryptogenic organizing pneumonia (Gr 3)
- Discontinuation in 2 patients due to BEX-related AEs
- Immune-related AEs reported at 3.0 and 6.0mg/kg across indications

DLTs: Dose-Limiting Toxicities, AEs: Adverse Events, TRAE: Treatment Related Adverse Event

# Bex Increases Bone Marrow Immune Activation

## CD8 T and NK cell numbers increase from screening to end-Cycle 3 in Bex-Aza patients

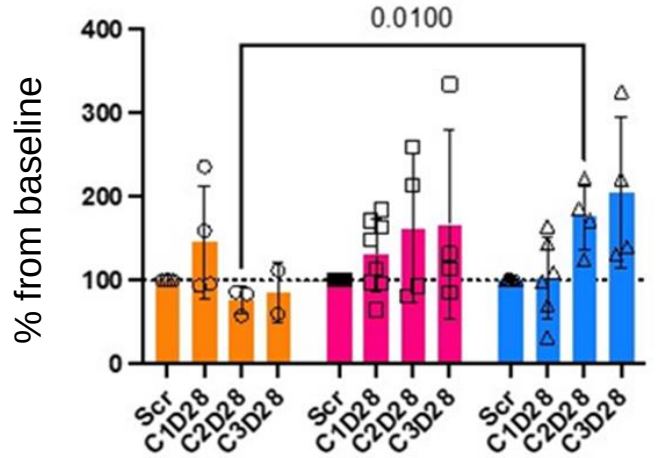


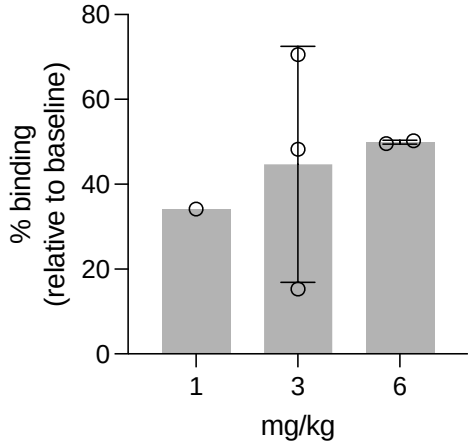

Upregulation of Antigen-presentation molecules on blasts during treatment across dose levels

* MESF = Molecules of Equivalent Soluble Fluorochrome, normalized fluorescence for comparison across timepoints

CD8 T cells




Target engagement in the bone marrow of HR MDS patients



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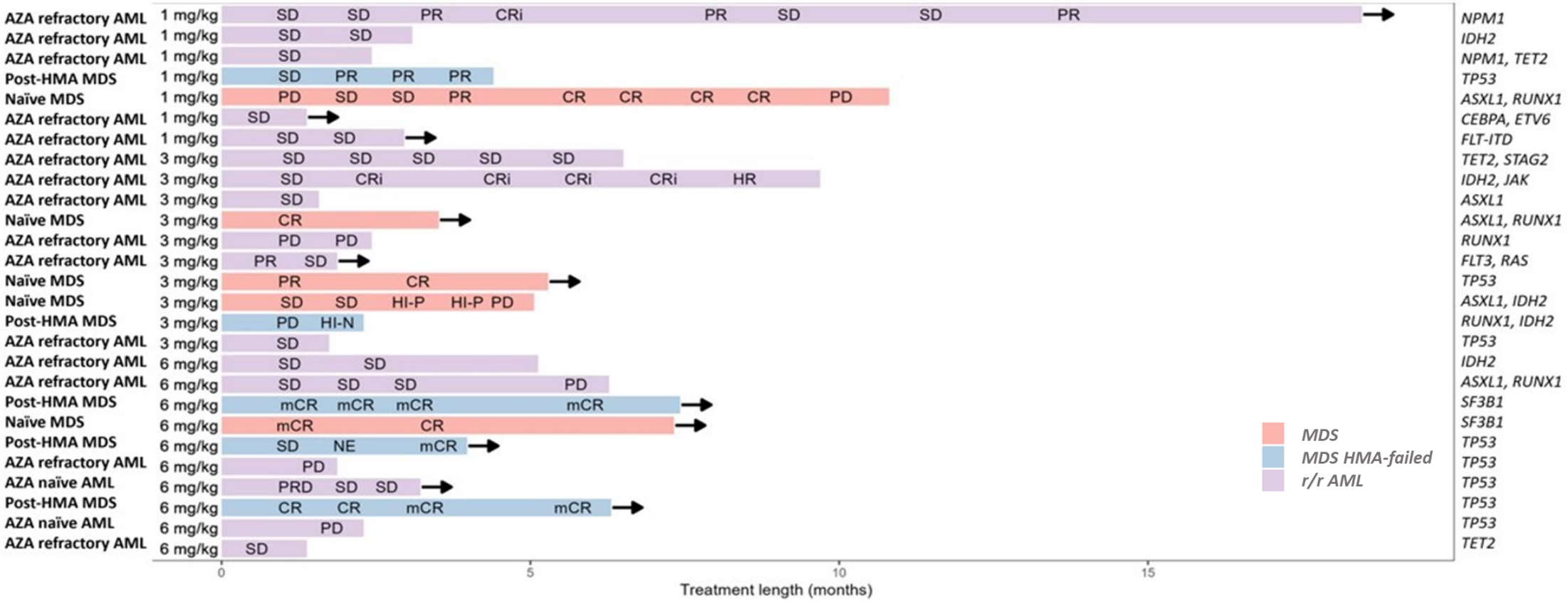
# Objective Responses Observed in ~50% of Patients Across Indications

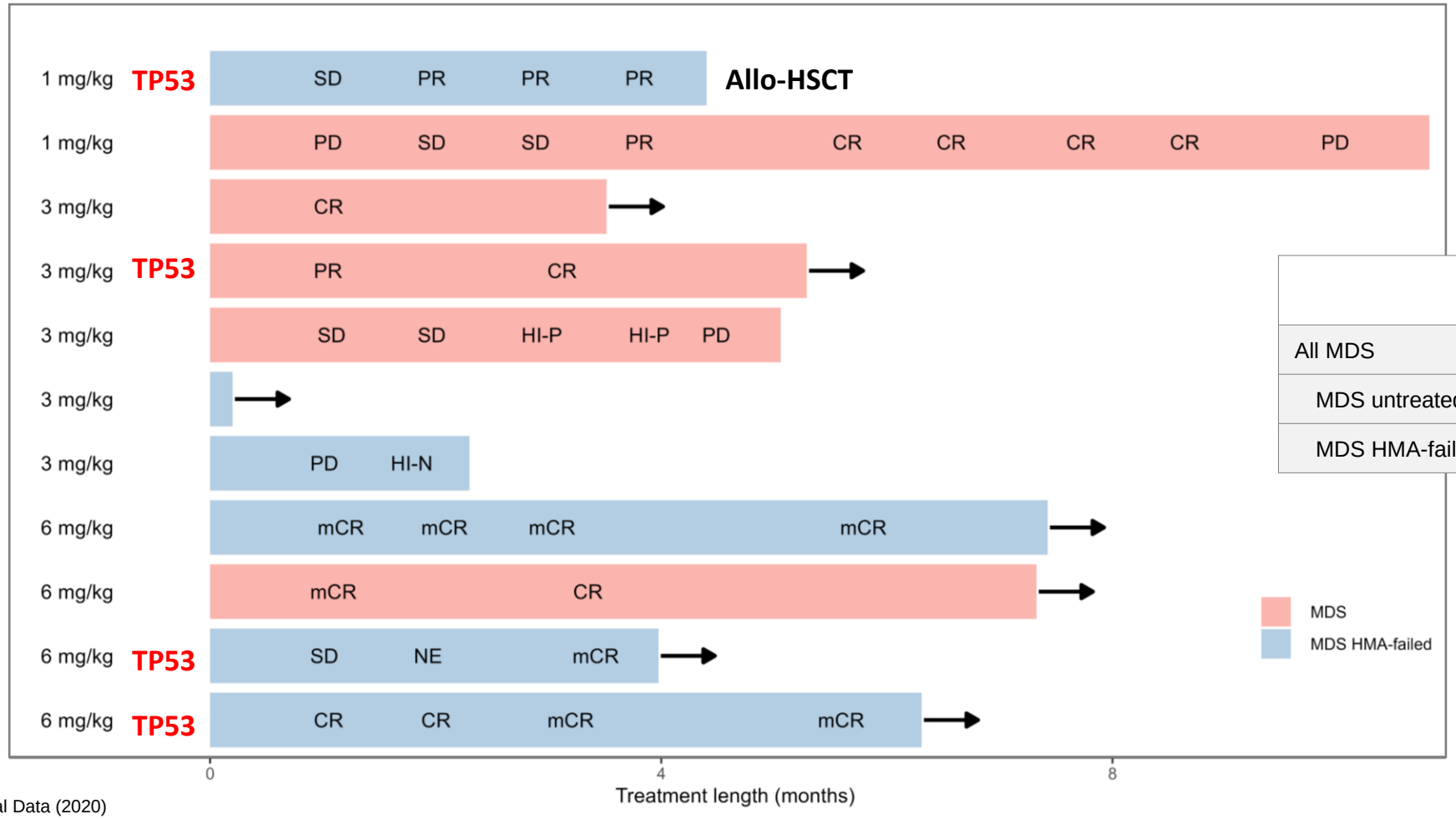
## Swimmer plot of doublet patients at 1.0, 3.0, and 6.0 mg/kg bexmarilimab combined with azacitidine (n=27). Readout November 18, 2023. Data released December 11, 2023 at ASH




Responses are deep and durable with 7/10 MDS patients achieving CR/mCR and one additional patient progressing to bone marrow transplant, majority of them being TP53 mutated

# High ORR achieved in both frontline HR MDS and HMA-failed MDS patients

## With a median overall survival in refractory MDS of just 4-6 months and no viable treatment options, patients now surpassing anticipated survival rates and maintaining remission



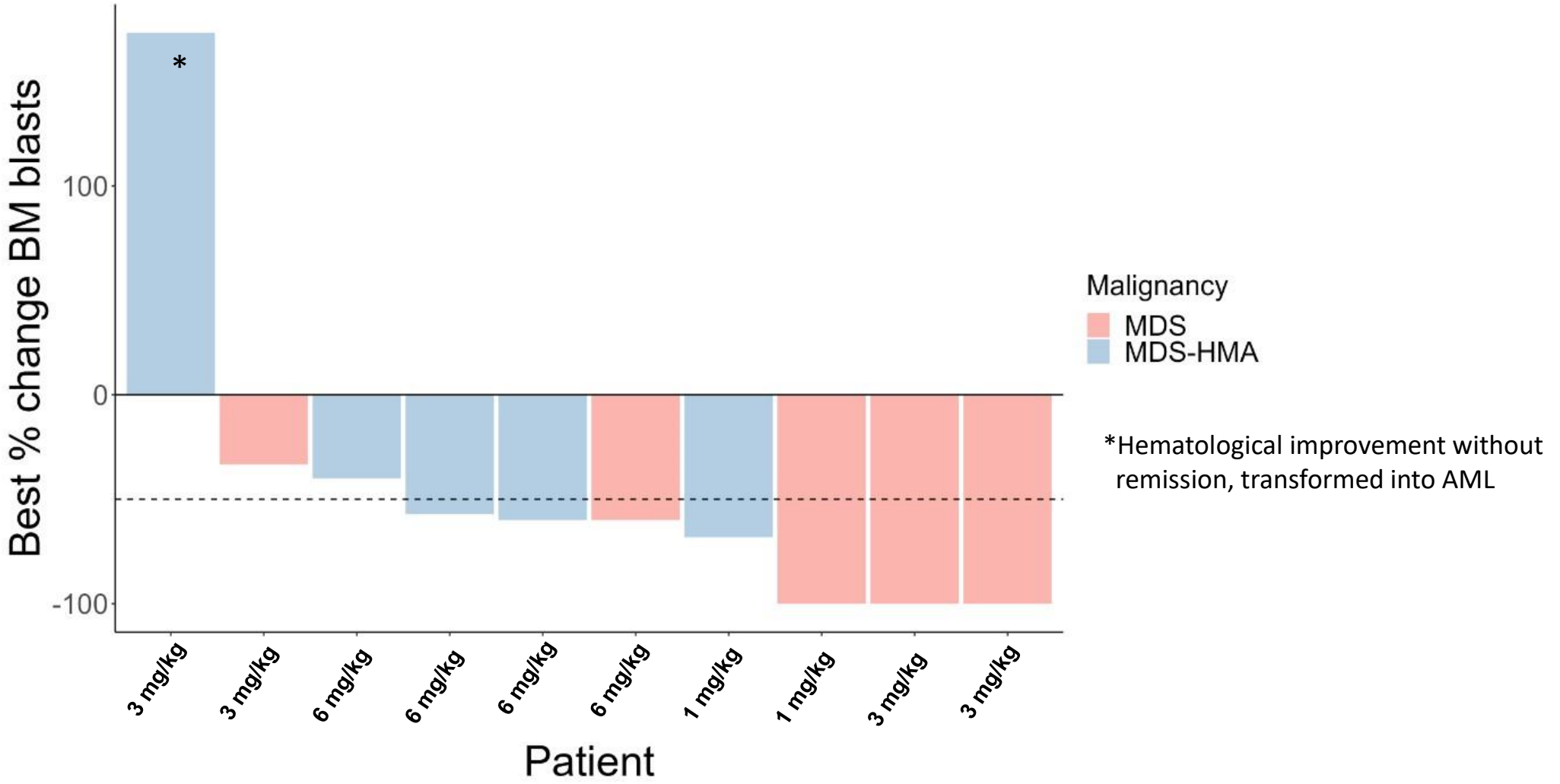

| | Number n | CR | mCR | PR/HI-P |
|---|---|---|---|---|
| All MDS | 10 | 5 (50%) | 2 (20%) | 3 (30%) |
| MDS untreated | 5 | 4 (80%) | | 1 (20%) |
| MDS HMA-failed | 5 | 1 (20%) | 2 (40%) | 2 (40%) |

Mutations in TP53 are detected in ~20% of MDS patients and stand out as one of the most significant adverse prognostic factors in the disease.*

*Global Data (2020)

# Significant Bone Marrow Blast Reduction in HR MDS Patients Treated with Bex + Aza

## Durable cancer blast eradication




*Hematological improvement without remission, transformed into AML

# Exceptional Data in Patients with High Unmet Medical Need

## Conclusions of BEXMAB

Patients with high-risk MDS who have failed HMA face a poor prognosis and a low probability to respond to salvage therapy

Remarkable and durable responses observed in combination with azacitidine in MDS

| | | |
|---|---|---|
| 13/28 patients with objective responses (ORs) observed across three dosing cohorts (doublet) | 5/5 MDS patients and 5/5 HMA-failed MDS patients show objective and durable responses | 7/10 MDS patients achieved CR/mCR and 1 additional patient with PR moved on to bone marrow transplant |

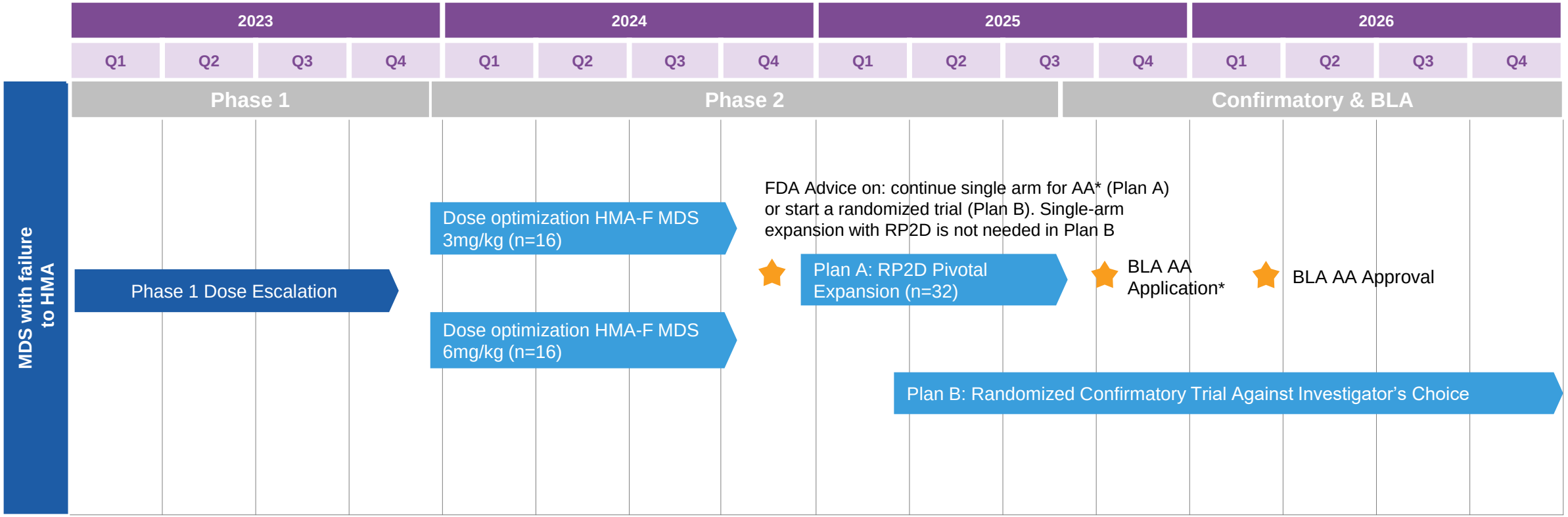
- Accelerated development focuses on HMA-failed MDS with large unmet need
- Phase 2 initiated with 3 mg/kg and 6 mg/kg doses selected in accordance with FDA's Project Optimus initiative guidance with possibility for accelerated approval

# Bexmarilimab has the Potential to Establish a New Standard of Care in Myeloid Malignancies

| | |
|---|---|
| **Mechanism of Action** | Bexmarilimab is a humanized monoclonal antibody to Clever-1 which reprograms myeloid blasts and primes the immune system to attack tumor cells |
| **Safety** | Bexmarilimab is well-tolerated in combination with standard-of-care azacitidine in patients with MDS and AML |
| **Efficacy** | Durable objective responses (ORs) observed in 50% of patients across three dosing cohorts (doublet) in both frontline and r/r settings. Significant overall response rates observed in both previously HMA-failed (5 out of 5) and higher-risk MDS (5 out of 5) patients |
| **Future development** | Given the encouraging and durable responses, Phase 2/3 development will focus on HMA-failed MDS as the first indication, seeking BLA filing as early as 2025 |

# Accelerated Development Plan for HMA-failed HR MDS

## Frontline HR MDS and r/r AML development plans explored separately




* Accelerated Approval (AA) may be achievable with outstanding efficacy from a single arm trial with on-going confirmatory trial, e.g. in HMA-failed MDS, otherwise see below
** Per FDA's recent guidance, start producing randomized data against comparator as early as possible. AA achievable with ORR of registrational trial and full approval with OS readout

# Outlook for the Next 12 Months

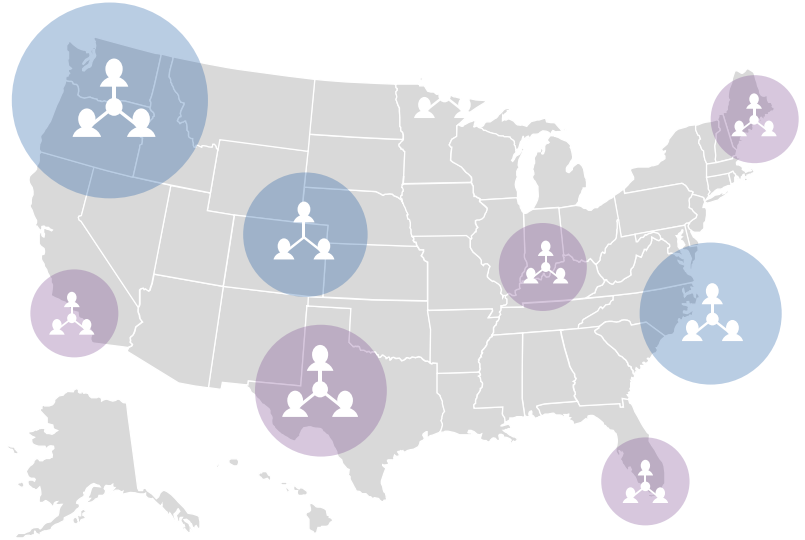
## Clinical development

**Bexmab**

- **Q1 2024** Phase 2 initiation on HMA-failed MDS
- **Q2 2024** Initial Phase 2 data read out
- **Q2 2024** Durability analysis of Phase 1 frontline HR MDS, HMA-failed MDS patients and r/r AML
- **Q4 2024** Full Phase 2 data read out

Regulatory interactions for additional designations & advice leading to registrational study design

**Corporate**



1. Continue to expand clinical network in US and Europe
2. Proceed with partnering discussions to competitive auction process
3. Potential for future expansion into a variety of haemato-oncology indications

# Bexmarilimab Pipeline

| Programs | Indication | Phase of Development | | | | Next Steps/Near-Term Milestones |
|---|---|---|---|---|---|---|
| | | Preclinical | Phase 1 | Phase 2 | Phase 3 | |
| **Hematological malignancies** | | | | | | |
| **bexmarilimab**<br>Expect first BLA filing as early as 2025 | HMA Failed MDS | | | BEXMAB Trial (LEUKEMIA & LYMPHOMA SOCIETY) | | Phase 2 readouts in Q2 and Q4 2024 |
| | Frontline HR MDS | | | SOC + BEX | | Waiting for dose from project Optimus phase 2 part of study |
| | r/r AML | | | SOC + BEX | | Awaiting to move to project Optimus phase 2 part of study |
| | CMML | | | SOC + BEX | | Recruiting |
| | Frontline AML non-fit for chemo | | | Aza + venetoclax + BEX | | Safety dose escalation |
| **Solid Tumors** | | | | | | |
| **bexmarilimab**<br>Targeting cold PD-1 refractory tumors | Solid tumors | | | MATINS Trial | | **Completed** |
| | Combo with CPIs in solid tumors | | | BEXCOMBO Trial | | IND approved and Phase 2 ready |

# Corporate Summary

## Potential to Establish New Standard of Care in Myeloid Malignancies

### Faron's Lead Asset

Proven anti-Clever-1 dual mechanism of action – immune activation and reduce viability of leukemic cells that are otherwise resistant to standard-of-care therapies

### Validated Platform

- ✓ Proof of principle for anti-Clever-1 Bex monotherapy demonstrated in MATINS Ph 1/2 trial in solid tumors (~200 pts)
- ✓ PoC for Bex in combination with SOC in MDS and r/r AML patients
- ✓ Significant Overall Response Rate in HR-MDS (5/5) and HMA-failed MDS (5/5 patients including patients with TP53 mutation, reported at ASH 2023

### Position

Potential for future expansion into a variety of haemato-oncology indications

Patent protection to 2037

Robust large-scale manufacturing process in place with readiness to move into registrational trials

Exceptional scientific founders & and leadership

### Milestones

BEXMAB Phase 1/2 readouts in 2Q and 4Q 2024

Followed by FDA registrational study plan and size

Actively pursuing Fast Track, Breakthrough, Accelerated Approval, and BLA filing

**AIM: FARN, First North: FARON** | **Boston, MA & Turku, Finland** | **Market Capitalization: EUR ~250M**

# An Overview of Faron

## Management Team

**Markku Jalkanen, PhD**
Founder & CEO

**Maija Hollmén, PhD**
Founder & CSO

**James O'Brien, MBA, CPA**
CFO

**Birge Berns, MD**
CMO

**Juho Jalkanen, MD, PhD, MSc**
Founder & COO

BIOTIE THERAPIES | ETH zürich | COGNITION Therapeutics | Johnson & Johnson | BIOTIE THERAPIES

UNIVERSITY OF TURKU | UNIVERSITY OF TURKU | Bristol Myers Squibb | Hoechst | UNIVERSITY OF TURKU

Stanford University | frontiers | Allergan | ICR The Institute of Cancer Research | TYKS Turku University Hospital

**Boston, MA / Turku, Finland**
**Global Headquarters**

**35+**
**Employees**

**2007**
**Year Founded**

# Experienced Leadership

## Scientific Advisors

**Sirpa Jalkanen, MD PhD**

Academician

**Jonathan Knowles, PhD**

Professor

**Tyler Curiel, MD, MPH**

Professor

**Naval G. Daver, MD**

Professor

**Mika Kontro, MD, PhD**

Adjunct Professor

**Cristophe Massard, MD, PhD**

Professor

**David Adams, MD**

Professor

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Non-Executive Director

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Non-Executive Director

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**Erik Ostrowski, MBA**

Non-Executive Director

## Transactional Advisor

**Leopoldo Zambeletti**

Advisor


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