A CLEVER Approach to **Fight Cancer** 

# **Faron Pharmaceuticals**

BEXMAB study update 19 July 2023

London AIM: FARN Helsinki First North: FARON

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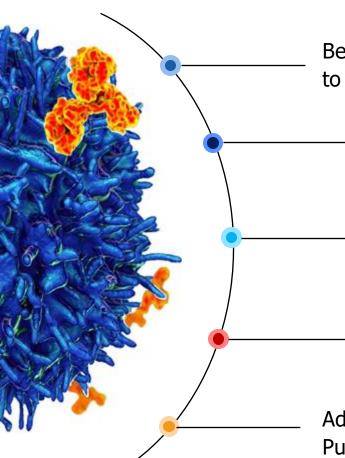
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# **Harnessing the Power of Macrophages to Conquer Immune Resistance**

CLEVER approach to sensitizing cancers to standard of care



Bexmarilimab is a humanized function blocking monoclonal antibody to Clever-1 and primes the immune system to attack tumors

Clever-1 is an immunosuppressive receptor on macrophages allowing tumor growth and metastases

Bex clinical data show increased immune activation as measured by IFN-γ supporting potential combinations with standard of care

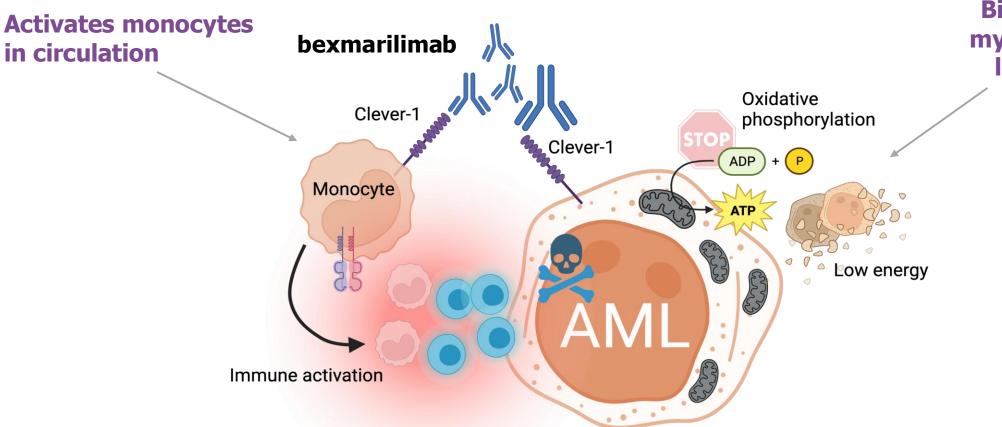
Lead Program in r/r AML and MDS HMA failure indications with early positive results in BEXMAB and MATINS clinical studies

Additional BEXMAB data expected 3Q 2023 followed by Phase 2 initiation; Pursuing Orphan Drug Status and Fast Track Designation



# **Dual Mode of Action in Hematological Malignancies**

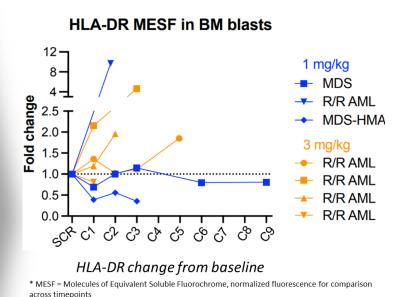
Clever-1 expressed on monocytes and myeloid cells and is abundant in AML



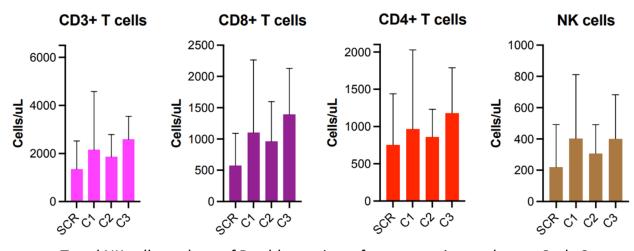
Binds directly to myeloid cells and lowers viability

# **Increase in Antigen Presentation and T Cell Activity Observed**

Bexmarilimab treatment results in immune activation in bone marrow at tested dose levels\*



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



T and NK cell numbers of Doublet patients from screening and up to Cycle 3.

Increase of T and NK cells in the BM of patients during treatment across dose levels

New data: IFN-gamma induction present in bone marrow of bex-treated patients

# **BEXMAB Phase 1/2 Study Evaluating Bexmarilimab with SoC**

Enrichment cohorts of DOUBLET ongoing

# POPULATION MDS r/r AML MDS failing on HMA based therapy Efficacy Evaluation (Phase 2) MDS r/r AML MDS failing on HMA based therapy MDS HMA failure

### **POPULATION**

Newly diagnosed AML that do not tolerate chemotherapy



### **TRIPLET**

azacitidine + venetoclax + bexmarilimab



### **Frontline AML**



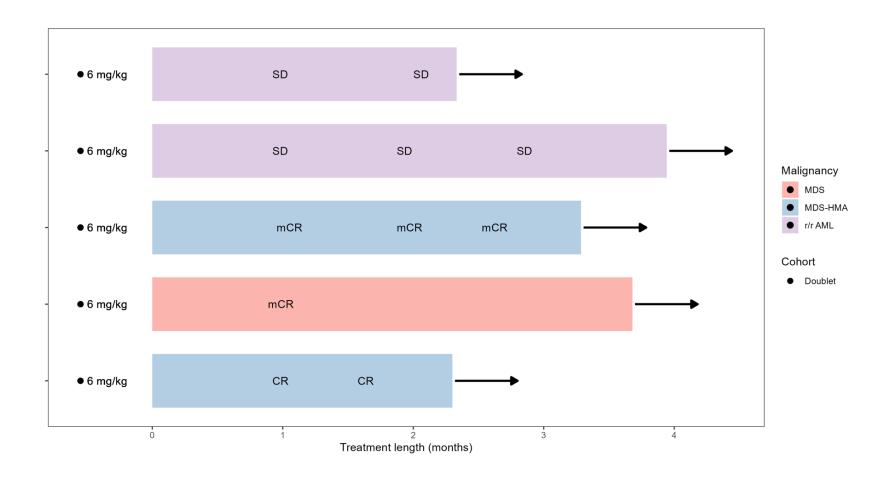
Supported by **Therapy Acceleration Program**funding by the **LLS** 

### Active sites: 4 in Finland and 2 in US

- Additional US sites Yale, UNC to open 3Q 2023
- Focusing on MDS HMA failure and r/r AML

# **Three Objective Responses Observed in the Latest Dosing Cohort**

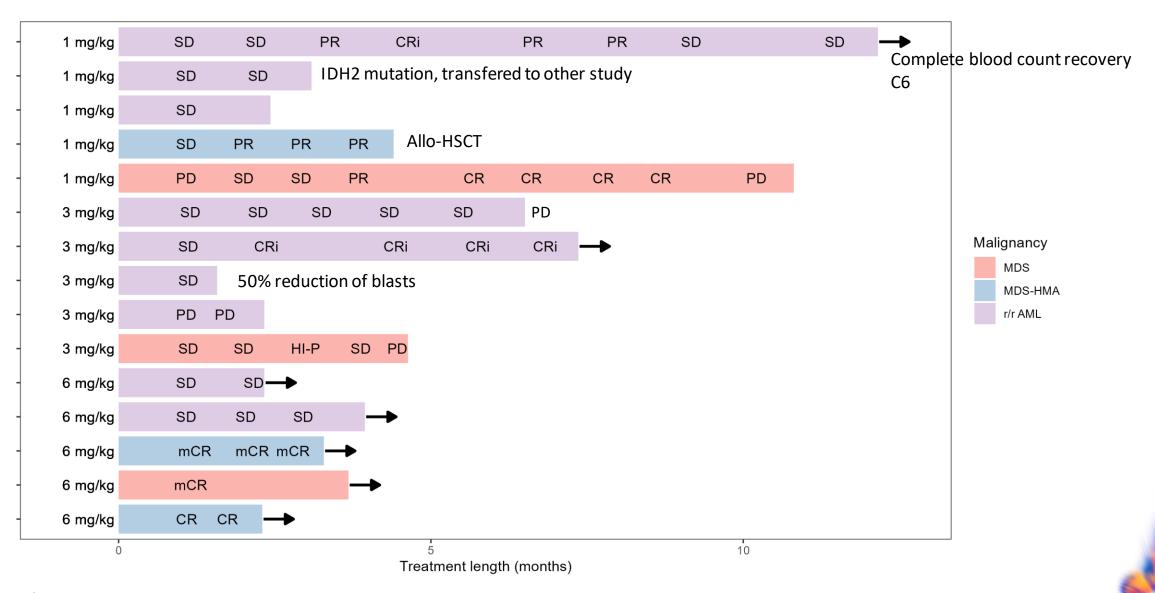
BEXMAB Doublet, 6 mg/kg dosing cohort





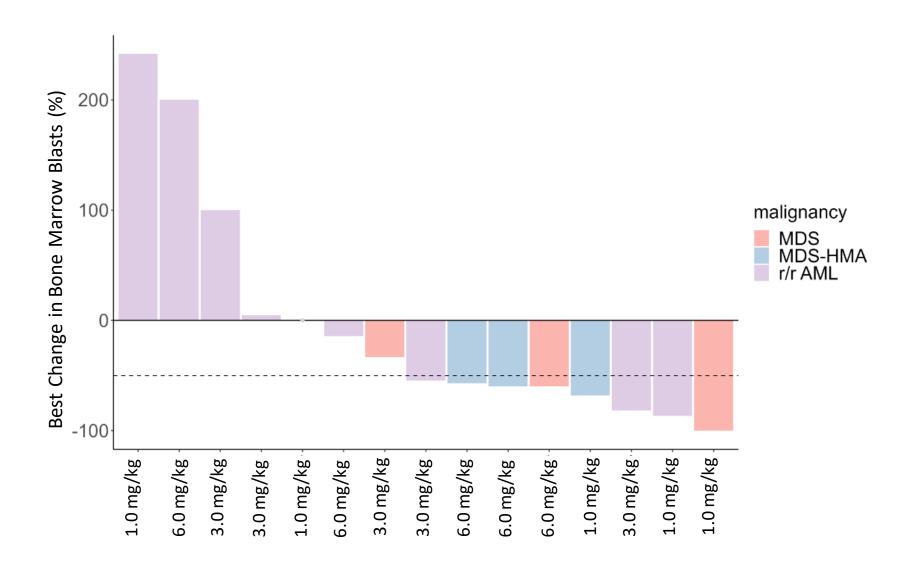
# **Responses Observed Across Indications and Dose Levels**

BEXMAB Doublet, data cut-of 12 July 2023



# Reduction of Bone Marrow Blasts in Majority of Patients

BEXMAB Doublet, data cut-off 12 July 2023



# **Bexmarilimab Related Adverse Events**

# BEXMAB Doublet, data cut-off 12 July 2023

Treatment-Related Adverse Events	# AEs (%) n=96
Any grade	8 (8)
Grade 3	1 (1)
Grade 5	1 (1)

Treatment-Related Adverse Events	Grade 1/2	Grade ≥ 3
Capillary Leak Syndrome	0 (0)	1 (1)
Constipation	3 (3)	0 (0)
Hemophagocytic lymphohistiocytosis	0 (0)	1 (1)
Nausea	1 (1)	0 (0)
Pyrexia	1 (1)	0 (0)
Vomiting	1 (1)	0 (0)

### **Short summary**

- No dose limiting toxicities (DLT)
- SAE related to BEX (in doublet):
  - HLH at 3.0 mg/kg (Gr 5)
  - CLS at 3.0 mg/kg (Gr 3)
- 2 Grade ≥ 3 AEs related to BEX (same as above)



# **Conclusion**

- Three of five patients in the 6 mg/kg bexmarilimab + azacitidine doublet cohort achieved objective responses (CR and mCR)
- > Eight of 15 objective responses (ORs) observed across the three dosing doublet cohorts
- One patient has stayed on treatment for 13 months
- Phase II/III development will focus on SoC relapsed/refractory AML or hypomethylating agent (HMA)-failed MDS
- ➤ Intention to file first market approval application (Biologics License Application to FDA) in H1 2025



# BEXMAB - Accelerated Development Plan for r/r AML/MDS HMA

Aiming to File BLA H1/2025

