

FARON

Faron Pharmaceuticals Ltd.

# **Business Update 11 February 2026**

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Webcast

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# AGENDA

- Highlights of 2025
- Key learnings in HR MDS
- Development plan
- Value proposition
- Offering and up-coming value inflection points
- Q&A



Business Update  
**Juho Jalkanen**  
CEO, Faron



Q&A session

# Highlights of 2025

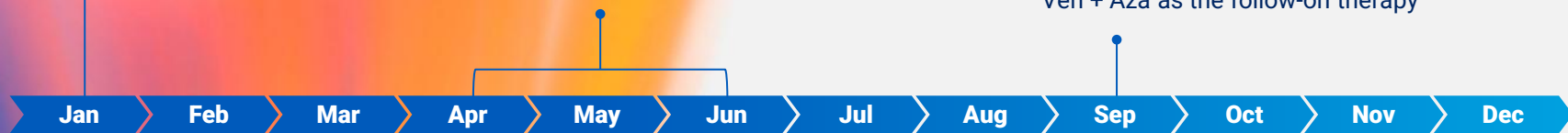
Completion of enrollment of both lastline and frontline HR MDS patients in the BEXMAB Phase I/II trial

Topline results of BEXMAB reported in April and oral presentations followed at ASCO and EHA

- Lastline (r/r MDS) ORR 63% (n = 32), with 13.4 mOS (ASCO)
- Frontline HR MDS ORR 72% (n = 18) with 28% CR rate (ASCO)
- EHA presentation showed deep bonemarrow responses and increasing frontline ORR to 85% (n = 20)

Negative VERONA results reported at SOHO Congress by Abbvie (Phase 3 Ven + Aza vs. Placebo + Aza in frontline HR MDS)

- Forensics:
  - 1) drop in efficacy due to dose interruptions,
  - 2) 30% of study population had low baseline blast count (<10%),
  - 3) 20% of placebo arm ended up receiving Ven + Aza as the follow-on therapy



Orphan designation for HR MDS from EMA & FDA

BEXMAB end-of-phase 2 meeting with the FDA emphasizing development in frontline HR MDS

- Move on to a Phase 2/3 study to test also 1mg/kg and show the contribution of each agent in frontline testing Bex + Aza vs. Placebo + Aza
- Accelerated Approval possibility based on response rate read-out (CR + CReq per IWG 2023 criteria)

BEXMAB oral presentation at ESMO showing deepening responses, bonemarrow modulation and clearing of complex cytogenetics (mutations) even in low blast count patients, with a further CR rate increase to 45% in 1st line HR MDS

# BEXMAB Highlights from American Society of Hematology annual conference, ASH 2025

## Frontline HR MDS up-dates: Deep and durable complete remissions (CRs)

- CR rate 45%\* with median duration of CR over 12 months and possibly increasing (historically 16-17%)
- CR rate in TP53m patients 70%\* with median duration of CR over 10 months (OS historically 8-10 months)
- 57% of frontline patients that were transfusion dependant became transfusion independent

## Relapsed/refractory MDS up-date:

- Last line survival increased to 14.5 months compared to previously reported 13.4 months (historically 5-6 months)

\*Nov 2025 data cut per protocol IWG 2006 criteria

# The most important discussions at ASH

1.

## The benefit of *bexmarilimab* in r/r MDS and possible accelerated approval in r/r MDS

- Investigators think that the benefit of Bex on top of Aza in last line HR MDS (r/r MDS) is clear and direct proof of the contribution of Bex
- Investigators want to produce more data in r/r MDS to prove their point and take it to the FDA
- Investigator Initiated Trial (IIT) in r/r MDS Bex + oral HMA is being planned by City of Hope (USA)

2.

## The in-built problem of Phase 3 studies in frontline HR MDS

- Phase 3 studies categorically fail on overall survival (OS) in frontline HR MDS due to post study drug treatments
- This means that OS is not actually a comparison of the intended study drugs, e.g. Ven+Aza vs. Placebo+Aza, but something else that doctors try after frontline failure

# The most important learnings after ASH

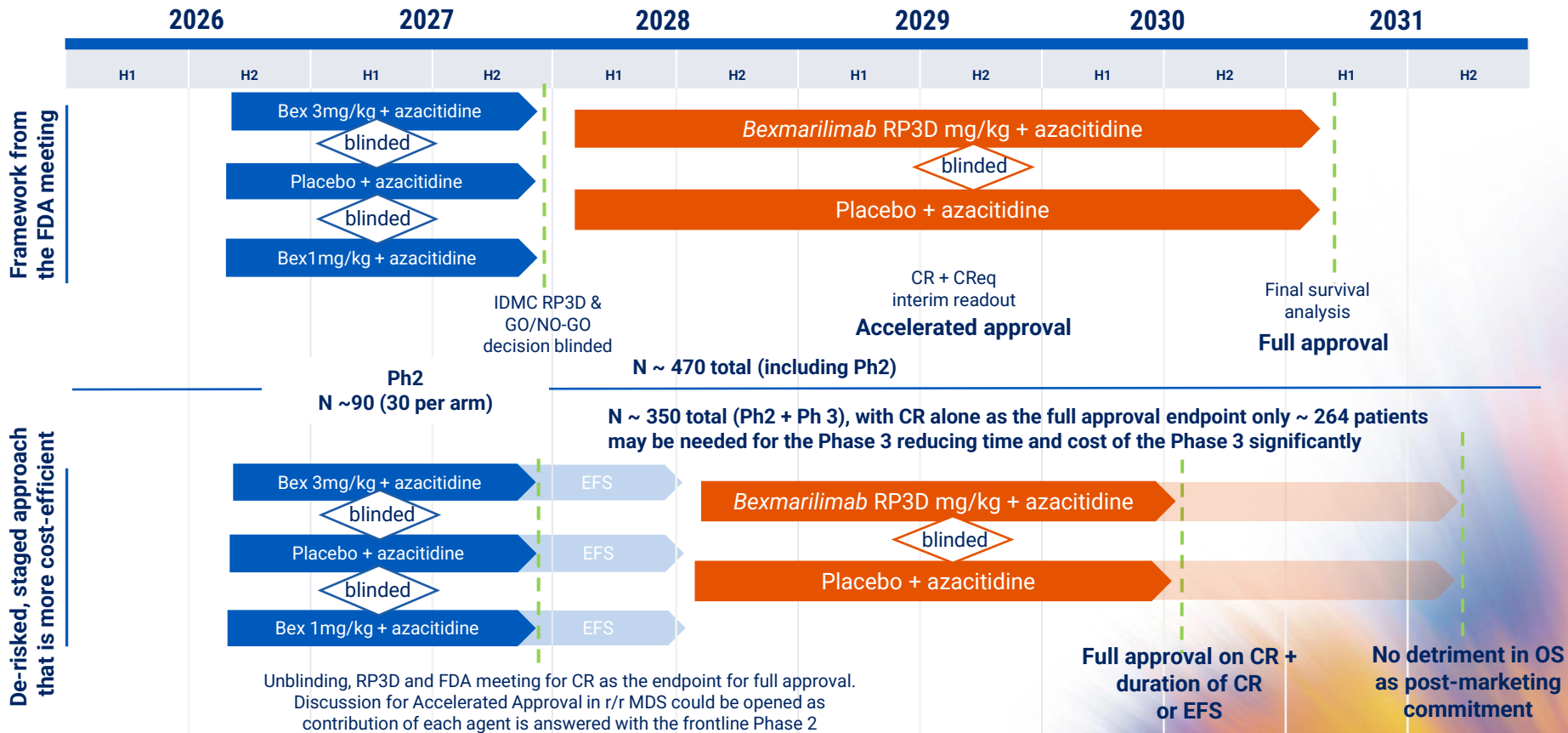
## Phase 3 frontline HR MDS studies categorically fail due to:

- Different cytogenetic abnormalities (Bex clears complex cytogenetic abnormalities, ESMO & ASH 2025)
- Variable blast percentages (Bex works across blast counts, even in low blast counts, ESMO 2025)
- Different bone marrow microenvironments (Bex is a disease modifying agent normalizing the BM, ESMO 2025)
- Old & frail population leading to competing mortality, dose reductions and early discontinuation (only with Bex 6mg/kg)
- Reliance on OS as the approval endpoint
  - Added toxicity erodes OS benefit (Bex does not add toxicity with doses < 6mg/kg)
  - OS is influenced by subsequent therapies and transplantation practice patterns (**real problem also for Bex**)

## Solution: Approval without reliance on OS

- FDA's MDS Guidance from 2025 allow CR alone with duration or possibly EFS as approval endpoints with supportive evidence and without a detrimental effect on OS (precedents Pevonedistat, Takeda)
- Already standard practice in frontline solid tumor trials

# Cost-effective execution of the Phase II/III mitigating the OS risk



# Value proposition – strong fundamentals of the core business

## Higher-risk myelodysplastic syndrome (HR MDS)

- Deadly form of leukemia with no novel treatments for 20 years
- Profound unmet need with 40 000 new patients each year in the US + EU5 and very limited competition

## Phase I/II completed with some of the best efficacy ever seen in frontline and lastline HR MDS

- 45% CR rate with duration over 12 months in frontline HR MDS
- 14.5 month mOS in last line HR MDS

## One of the best safety profiles ever reported for a HR MDS drug candidate

- Induction of hematopoiesis and 57% transfusion independence achieved
- Bex does not cause more  $\geq$  grade 3 anemia and neutropenia than reported with single agent Aza

## In one of the worst possible populations of HR MDS

- 57% very high risk per IPSS-M, higher risk population than comparative data sets that have weaker efficacy & safety

## With a cost-effective development plan to mitigate previous Phase 3 risks in frontline HR MDS

- Staged approach starting with randomized Phase 2 to confirm signal and approval endpoint(s) before final Phase 3

## Offering significant value inflection potential with new randomized Phase 2 frontline HR MDS readout & generating data in up to 5 new indications

# Offering new value inflection points with the following

- Randomized data from Faron sponsored Phase II HR MDS trial comparing *bexmarilimab* in combination with azacitidine against azacitidine alone
- Further data in r/r MDS from an IIT to support regulatory interactions
- Proof-of-concept data through IITs in:
  - Soft tissue sarcoma
  - HER2- / ER+ breast cancer
  - Melanoma
  - Non-small cell lung cancer
  - AML

**Q&A**

A graphic element of the FARON logo, consisting of several thin, overlapping lines radiating upwards and outwards from a central point at the bottom. The lines are colored in a gradient from blue to orange and yellow, creating a sense of motion or energy.

**FARON**

**Thank you**

A graphic element of the FARON logo, consisting of several thin, overlapping lines radiating upwards from a central point, transitioning in color from blue at the base to yellow and orange at the tips.

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