

Inside Information: BEXMAB Phase II trial met its primary endpoint in treatment-resistant High Risk MDS (r/r HR MDS)

Key Highlights

- Topline read-out from the Phase II BEXMAB trial confirms earlier positive findings in both frontline and relapsed/refractory higher-risk myelodysplastic syndrome (HR MDS) patients
- The combination of *bexmarilimab* and azacitidine remains very well tolerated
- Full data has been submitted to the 2025 American Society of Clinical Oncology (ASCO) Annual Meeting
- Faron is planning for a Phase III trial, pending U.S Food and Drug Administration (FDA) End of Phase II meeting Feedback

TURKU, FINLAND - Faron Pharmaceuticals Ltd. (AIM: FARN, First North: FARON), a clinical-stage biopharmaceutical company focused on developing novel immunotherapies, today announced positive topline results of the BEXMAB trial, which shows a high overall response rate (ORR) among both frontline as well as relapsed/refractory (r/r) HR MDS patients treated with a combination of *bexmarilimab* and azacitidine.

According to this first fully enrolled Phase II analysis, the treatment continues to be well tolerated without any dose-limiting toxicity in r/r HR MDS patients with no other currently effective treatment options. A high objective response rate of 63% was observed in this initial data cut. The median overall survival remains at the same level as previously reported. Among treatment naïve (frontline phase 1) HR MDS patients, an ORR of 76% was observed. Many patients are still early in their treatment, which means responses may deepen over time and results are subject to minor changes as data matures. The full data has been submitted to the 2025 ASCO Annual Meeting.

“This is one of the strongest data set ever seen in an all-comer population of treatment resistant HR MDS”, says Dr. Juho Jalkanen, CEO of Faron Pharmaceuticals. “There is a significant unmet need in the treatment of HR MDS, as drug development in HR MDS and macrophage re-programming has proven to be extremely challenging, with a lot of previous failures. What really makes *bexmarilimab* stand out in this field is its good safety profile combined with very high efficacy especially in last line HR MDS. This gives us conviction that *bexmarilimab* is the long-awaited drug to overcome treatment resistance”.

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About BEXMAB

The BEXMAB study is an open-label Phase I/II clinical trial investigating *bexmarilimab* in combination with standard of care (SoC) in the aggressive hematological malignancies of acute myeloid leukemia (AML) and myelodysplastic syndrome (MDS). The primary objective is to determine the safety and tolerability of *bexmarilimab* in combination with SoC (azacitidine) treatment. Directly targeting Clever-1 could limit the replication capacity of cancer cells, increase antigen presentation, ignite an immune response, and allow current treatments to be more effective. Clever-1 is highly expressed in both AML and MDS and associated with therapy resistance, limited T cell activation and poor outcomes.

About *bexmarilimab*

Bexmarilimab is Faron's wholly owned, investigational immunotherapy designed to overcome resistance to existing treatments and optimize clinical outcomes, by targeting myeloid cell function and igniting the immune system. *Bexmarilimab* binds to Clever-1, an immunosuppressive receptor found on macrophages leading to tumor growth and metastases (i.e. helps cancer evade the immune system). By targeting the Clever-1 receptor on macrophages, *bexmarilimab* alters the tumor microenvironment, reprogramming macrophages from an immunosuppressive (M2)

state to an immunostimulatory (M1) one, upregulating interferon production and priming the immune system to attack tumors and sensitizing cancer cells to standard of care.

About Faron Pharmaceuticals Ltd

Faron (AIM: FARN, First North: FARON) is a global, clinical-stage biopharmaceutical company, focused on tackling cancers via novel immunotherapies. Its mission is to bring the promise of immunotherapy to a broader population by uncovering novel ways to control and harness the power of the immune system. The Company's lead asset is *bexmarilimab*, a novel anti-Clever-1 humanized antibody, with the potential to remove immunosuppression of cancers through reprogramming myeloid cell function. *Bexmarilimab* is being investigated in Phase I/II clinical trials as a potential therapy for patients with hematological cancers in combination with other standard treatments. Further information is available at www.faron.com.