Faron Pharmaceuticals Ltd | Company announcement | October 20, 2025 at 09:00:00 EEST

Updated BEXMAB Phase I/II Data presented at ESMO 2025 shows further improvement, strengthening the clinical profile of *bexmarilimab* in treatment-naÃ¯ve HR-MDS patients with an 85%ORR and a 45%CR rate, bolstered by pharmacodynamic insights

New biomarker data reveals strong correlation between target engagement and clinical response with 100% ORR in treatment-naÃ¯ve, low blast count (<5%) patients

Key highlights:

- Bexmarilimab and azacitidine combination resulted in an 85% objective response rate (ORR; 17/20 evaluable patients) and a 45% complete remission (CR) rate (9/20) in treatment-naÃ¯ve patients with higher-risk myelodysplastic syndrome (HR-MDS)
- 55% (11/20) of treatment-naÃ¯ve patients with HR-MDS showed fullÂ clearance of bone marrow (BM) blasts
- Deeper BM engagement in treatment-naÃ¯ve patients with <5% bone marrow blasts at baseline translated to 100% ORR, one of the best results ever reported in this patient population
- 23% of patients across the BEXMAB study were successfully bridged to a potentially curative stem cell transplant (SCT)
- Faron will be hosting a virtual webinar to discuss the updated BEXMAB data presented at ESMO 2025 on 23 October at 4pm EEST/9am ET.

Turku, Finlandâ€“ Faron Pharmaceuticals Ltd. (AIM: FARN, First North: FARON), a clinical-stage biopharmaceutical company focused on tackling cancers through novel immunotherapies, today announced that updated data from the Phase I/II BEXMAB study continues to show significant clinical activity for *bexmarilimab*. The findings, presented in an oral session at the European Society for Medical Oncology (ESMO) Congress 2025 by Dr. Mika Kontro from Helsinki University Hospital, not only confirm the high response rates seen in earlier analyses but also provide a clear pharmacodynamic rationale linking the drugâ€™s mechanism of action directly to patient outcomes. Â

The BEXMAB study evaluates *bexmarilimab* (1, 3, or 6 mg/kg weekly in 28-day cycles), a first-in-class monoclonal antibody targeting the Clever-1 receptor, in combination with azacitidine, a standard-of-care hypomethylating agent (HMA). By blocking Clever-1, *bexmarilimab* reprograms macrophages in the bone marrow, enhancing anti-tumor immunity. The data presented at ESMO 2025 included 21 treatment-naÃ¯ve (20 evaluable for efficacy) and 32 relapsed/refractory (r/r) HMA-failed patients with HR-MDS.

The updated data presented at ESMO 2025 reinforces the efficacy previously observed for the *bexmarilimab* and azacitidine combination. In 20 evaluable treatment-naÃ¯ve patients, the study confirmed an 85% ORR and a 45% CR rate. These high response rates were observed in a difficult-to-treat population, where over 66% of patients were classified as high to very high risk at baseline. The combination also showed robust activity in patients with high-risk mutations like *mTP53*, achieving an ORR of 78%. Â

In the r/r HMA-failed population (n=32), the combination achieved a 63% ORR and a median overall survival (mOS) of 13.4 months. Notably, nearly a third of these patients (31.3%) had received prior therapy with the Bcl-2 inhibitor venetoclax. Â

About 23% of patients across the BEXMAB study were successfully bridged to a potentially curative stem cell transplant (SCT).

The most significant update is the new pharmacodynamic data that provided a clear biological explanation for the strong clinical results. The analysis showed a statistically significant correlation (p=0.0006) between deeper engagement of the Clever-1 target in the bone marrow and a positive clinical response. This correlation was particularly striking in the subgroup of treatment-naÃ¯ve patients with <5% bone marrow blasts at baseline (38% of the cohort), a population for which effective, non-intensive therapies are urgently needed. In these patients, deeper target engagement translated to a 100% ORR, supporting *bexmarilimabâ€™s* unique mechanism of action as a truly disease modifying agent, differentiating it from other investigational HR-MDS therapies, such as Bcl-2 inhibitors. For patients with a higher blast count (>5% at baseline), the ORR remained high at 75%.

With the result of this data, Faron is preparing for the next stage of development. Following guidance from the FDA announced on 18 August 2025, the Company has begun preparations for the dose-optimization stage of its Phase II/III trial for *bexmarilimab*, after which the trial will transition into the registrational stage with accelerated approval possibility. The combination therapy continues to be well-tolerated, with a safety profile similar, or even better to, azacitidine monotherapy. Only 36% of treatment-emergent adverse events were considered related to *bexmarilimab*, with no Grade 5 events.

Dr. Mika Kontro, MD, PhD, Associate Professor at University of Helsinki and Helsinki University Hospital Comprehensive Cancer Center, Department of Hematology said, â€œ*The BEXMAB data are encouraging, and the new biomarker analysis provides a clear pharmacodynamic rationale for bexmarilimabâ€™s clinical activity. The direct correlation between how deeply we engage the Clever-1 target in the bone marrow and a patientâ€™s clinical response reinforces the drugâ€™s mechanism. The 100% ORR in patients with low blast counts suggest that this therapy may help in a population where current investigational treatments, including Bcl-2 inhibitors, have significant limitations.â€*

Dr. Maija HollmÃ©n, PhD, Chief Scientific Officer of Faron Pharmaceuticals, added, â€œ*The selection of this BEXMAB data for an oral presentation at ESMO is a significant external validation of our science and the clinical potential of bexmarilimab. These findings help us understand why the drug works and for whom it works best. The clear biomarker impact in the bone marrow and unique efficacy in patients with low blast counts highlights Bexâ€™s ability to change the course of the disease and provides a solid foundation for our late-stage clinical development, bringing this promising therapy to patients who desperately need better options.*â€

To register for the event visit: ESMO 2025. The details of the ESMO oral presentation are as follows:

Presentation title: Macrophage reprogrammer Bexmarilimab Plus Azacitidine in Myelodysplastic Syndrome: PK/PD and biomarker results from the Phase I/II BEXMAB Study

Presented by: Dr. Mika Kontro

Session type and title: Mini Oral Session: Haematological Malignancies

Room: Solingen Auditorium - Hall 23

Session date & time: Oct 19, 2025 (9:31 to 9:36 am CEST)

Abstract no.: 1249MO

This announcement contains inside information for the purposes of Article 7 of the EU Regulation 596/2014 ("MAR") and Article 7 of MAR as incorporated into UK domestic law by virtue of the European Union (Withdrawal) Act 2018 ("UK MAR").

For more information, please contact:

IR Partners, Finland **(Media)** Kare Laukkanen	+358 50 553 9535 / +44 7 469 766 223 kare.laukkanen@irpartners.fi
FINN Partners, US **(Media)Â** Alyssa PaldoÂ	+1 847 791-8085Â alyssa.paldo@finnpartners.com
Cairn Financial Advisers LLP **(Nominated Adviser and Broker)** Sandy Jamieson, Jo Turner	+44 (0) 207 213 0880
Sisu Partners Oy **(Certified Adviser on Nasdaq First North)** Juha Karttunen Jukka JÃ¤rvelÃ¤	+358 (0)40 555 4727 +358 (0)50 553 8990

About BEXMAB

The BEXMAB study is an open-label Phase I/II clinical trial investigatingÂ *bexmarilimab*Â 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 ofÂ *bexmarilimab*Â 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.

AboutÂ *bexmarilimab*

*Bexmarilimab*Â is Faronâ€™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.Â *Bexmarilimab*Â 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,Â *bexmarilimab*Â 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 Companyâ€™s lead asset isÂ *bexmarilimab*, a novel anti-Clever-1 humanized antibody, with the potential to remove immunosuppression of cancers through reprogramming myeloid cell function.Â *Bexmarilimab*Â 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 atÂ www.faron.com.

Forward-Looking Statements

Certain statements in this announcement are, or may be deemed to be, forward-looking statements. Forward looking statements are identified by their use of terms and phrases such as â€believeâ€, â€couldâ€, â€œshouldâ€, â€œexpectâ€, â€œhopeâ€, â€œseekâ€, â€envisageâ€, â€estimateâ€, â€intendâ€, â€mayâ€, â€planâ€, â€potentiallyâ€, â€willâ€ or the negative of those, variations or comparable expressions, including references to assumptions. These forward-looking statements are not based on historical facts but rather on the Directorsâ€™ current expectations and assumptions regarding the Companyâ€™s future growth, results of operations, performance, future capital and other expenditures (including the amount, nature and sources of funding thereof), competitive advantages, business prospects and opportunities. Such forward-looking statements reflect the Directorsâ€™ current beliefs and assumptions and are based on information currently available to the Directors.

A number of factors could cause actual results to differ materially from the results and expectations discussed in the forward-looking statements, many of which are beyond the control of the Company. In addition, other factors which could cause actual results to differ materially include the ability of the Company to successfully license its programs within the anticipated timeframe or at all, risks associated with vulnerability to general economic and business conditions, competition, environmental and other regulatory changes, actions by governmental authorities, the availability of capital markets or other sources of funding, reliance on key personnel, uninsured and underinsured losses and other factors. Although any forward-looking statements contained in this announcement are based upon what the Directors believe to be reasonable assumptions, the Company cannot assure investors that actual results will be consistent with such forward-looking statements. Accordingly, readers are cautioned not to place undue reliance on forward-looking statements. Subject to any continuing obligations under applicable law or any relevant AIM Rule requirements, in providing this information the Company does not undertake any obligation to publicly update or revise any of the forward-looking statements or to advise of any change in events, conditions or circumstances on which any such statement is based.