Faron Pharmaceuticals Ltd | Company announcement | August 06, 2025 at 09:00:00 EEST

Inside Information: Complete remission rate in frontline HR-MDS patients rose from 28% to 43% in latest data cut, confirming the deepening of responses over time.

TURKU, FINLANDâ€“ Faron Pharmaceuticals Ltd. (AIM: FARN, First North: FARON), a clinical-stage biopharmaceutical company focused on tackling cancers through novel immunological pathways, today announced an increase in the complete remission (CR) rate in patients with frontline or treatment-naÃ¯ve high-risk myelodysplastic syndrome (HR-MDS), based on updated efficacy data from its Phase 1/2 BEXMAB trial.

According to the investigator-assessed response using IWG 2006 criteria, as per protocol, the CR rate (as explained below) has increased to 43% (9 out of 21 patients), a substantial improvement from the 28% rate, seen in the earlier data cut. This data builds on the phase II results featured in recent oral presentation at the 2025 American Society of Clinical Oncology (ASCO) congress. This improvement in CR is a result of patient responses improving as they continue longer on the combination therapy of *bexmarilimab* and the standard-of-care, azacitidine. This updated efficacy data was prepared for an upcoming End-of-Phase 2 (EOP2) meeting with the US Food and Drug Administration (FDA).

CR signifies a return to normal blood cell counts and bone marrow cellularity. This rate was measured using the internationally recognized and stringent, protocol pre-specified criteria. The 43% CR rate achieved with the *bexmarilimab* combination is more than double the 16-17% historical rate seen in patients treated with azacitidine alone, representing a major therapeutic advance. Earlier data from the BEXMAB study had also reported an encouraging 50% composite CR rate (cCR) in frontline HR-MDS patients, and in essence more and more of these cCR responses are turning into CR over time.

â€œThe continued maturation of the BEXMAB data demonstrates *bexmarilimab*â€™s profound impact as a disease-modifying agent," said **Dr. Petri Bono, Chief Medical Officer of Faron**. â€œSeeing the CR rate strengthen over time to 43%, which complements the robust 50% cCR we have already reported, is very encouraging. It provides us with two compelling and clinically meaningful data sets for discussion with the FDA and gives us confidence in proposing a randomized registrational trial designed for accelerated approval with either CR or cCR as the primary endpoint.â€

For more information, please contact:

IR Partners, Finland (media)
Riina Tuominen
+358 44 313 5005
riina.tuominen@irpartners.fi

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
Phone: +44 (0) 207 213 0880

Sisu Partners Oy, Certified Adviser on Nasdaq First North
Juha Karttunen
Phone: +358 (0)40 555 4727
Jukka JÃ¤rvelÃ¤
Phone: +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.