

Faron Pharmaceuticals Ltd.

("Faron" or the "Company")

Inside information: Faron Announces First HMA-failed MDS Patient Dosed with *Bexmarilimab* as part of Phase 2 of BEXMAB Trial

- *Phase 2 of the trial aims to recruit 32 patients with HMA-failed MDS and to provide final and optimized dosing for registrational study*
- *Company is exploring further development opportunities within the *bexmarilimab* program in hematological cancer patients following positive feedback from the recent ASH congress*

Company Announcement, Inside Information

TURKU, Finland / BOSTON, Massachusetts – January 9, 2024 – Faron Pharmaceuticals Ltd. (AIM: FARN, First North: FARON), a clinical-stage biopharmaceutical company pursuing a CLEVER approach to reprogramming myeloid cells to activate anti-tumor immunity in hematological and solid tumor microenvironments, today announced that the first patient has been dosed in Phase 2 of the BEXMAB trial that evaluates the safety and efficacy of *bexmarilimab*, in combination with standard of care (SoC) in patients with hypomethylating agents (HMAs)-refractory or relapsed myelodysplastic syndrome (MDS), an aggressive myeloid leukemia with very few treatment options.

The ongoing, randomized parallel-assigned Phase 2 part is enrolling 32 HMA-failed MDS patients at 3 mg/kg and 6 mg/kg dose levels of *bexmarilimab*. Dose levels have been selected in accordance with the FDA's Project Optimus initiative, which aims to reform the paradigm of dose optimization and selection in oncology drug development. Patients are being randomized 1:1 between the doses before moving into a Phase 2/3 study expansion. As previously detailed, data from the first 20 patients (10 per dose group) will be reviewed for exposure-to-benefit to compare the two selected dose levels. Post selection of final dosing, Faron intends to discuss a potential registrational study plan with the FDA.

"Dosing of the first patients in this advanced part of the BEXMAB study is another significant milestone in the *bexmarilimab* program, and we want to thank our clinical network again for the rapid advancement of our program," said Dr. Birge Berns, Chief Medical Officer of Faron. "Refractory and relapsed MDS represents a significant therapeutic challenge and based on the [recently announced data at ASH](#) from the Phase 1 part of this trial, we believe that *bexmarilimab* has the potential to save and improve the lives of HMA-failed MDS patients."

Faron is currently opening additional sites to speed up the trial's rapid recruitment, ahead of a future registrational study. The Company's key focus is to pursue an accelerated path to approval in refractory higher risk MDS, where no treatment option exists.

Given the positive results to date, the Company will also explore the immunotherapy's potential in low risk MDS as well as chronic myelomonocytic leukaemia (CMML) patients, who are currently treated with HMA-based therapies treatment upon worsening of disease and consider further development and expansion opportunities with *bexmarilimab* in hematological cancers in the form of partnerships.

For more information on BEXMAB, please visit ClinicalTrials.gov and reference Identifier [NCT05428969](https://ClinicalTrials.gov/ct2/show/study/NCT05428969).

This announcement contains inside information for the purposes of Article 7 of Regulation (EU) No 596/2014 ("MAR").

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About BEXMAB

The BEXMAB study is an open-label Phase 1/2 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.

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 "believe", "could", "should", "expect", "hope", "seek", "envisage", "estimate", "intend", "may", "plan", "potentially", "will" 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 Directors' current expectations and assumptions regarding the Company'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 Directors' 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.