Faron Pharmaceuticals Ltd.

("Faron" or the "Company")

Insider information: Faron Initiates Phase 2 Part of BEXMAB Study of *Bexmarilimab* in HMA-failed MDS

- *MDS patients who have failed prior HMA therapy selected as first indication to advance into Phase 2*
- *3 mg/kg and 6 mg/kg doses selected in accordance with FDA's Project Optimus initiative guidance*
- *Phase 2 part of the study will recruit 32 HMA-failed MDS patients for 1:1 dose randomization with possible data release after 20 patients have received more than two treatment cycles*

Company announcement, Inside Information

TURKU, Finland / BOSTON, Massachusetts – November 06, 2023 – Faron Pharmaceuticals Ltd. (AIM: FARN, First North: FARON), a clinical-stage biopharmaceutical company pioneering macrophage reprogramming for effective anticancer immunotherapies, today announces that based on guidance from the U.S. Food and Drug Administration (FDA), hypomethylating agents (HMAs)-refractory or relapsed myelodysplastic syndromes (MDS) has been selected as the initial indication to advance to Phase 2 in the BEXMAB study investigating *bexmarilimab* in combination with standard of care (SoC).

The BEXMAB study is a multicenter study, taking place in Finland and the U.S., evaluating the safety and efficacy of *bexmarilimab*, a novel anti-Clever-1 humanized antibody, with SoC in patients with aggressive myeloid leukemias.

The Phase 2 part of the BEXMAB trial will enroll a total of 32 patients with HMA-failed MDS. Patients will be randomized 1:1 between the selected recommended doses for expansion (RDE) of 3 mg/kg or 6 mg/kg *bexmarilimab* before moving into a Phase 2/3 extension of the study. Data from the first 20 patients (10 per group) will be reviewed for exposure benefit for the two selected dose levels. Post selection of final dosing Faron intends to discuss a potential registrational study plan with the FDA.

"Expansion of the BEXMAB study into Phase 2 provides an opportunity to build on the very promising findings we have already observed among patients treated with *bexmarilimab* in the earlier stage of the trial," said Dr. Mika Kontro, Associate Professor, Helsinki University Hospital Comprehensive Cancer Center and Principal Investigator of the BEXMAB trial. "With two good doses now established for further investigation we hope to rapidly generate further, robust data to support the potential of this novel immunotherapy in a patient group with too few treatment options available to them."

Data from the Phase 1 part of the study have demonstrated that optimal target engagement can be achieved with 3 mg/kg dosing. The highest immune activation, as observed in the accumulation of activated immune cells in patients' bone marrow, was observed in both 3 mg/kg and 6 mg/kg cohorts. Both dose levels have been safe and well tolerated to date.

The 3 mg/kg and 6 mg/kg doses were selected in accordance with the FDA's Project Optimus initiative, which aims to reform the paradigms of dose optimization and selection in oncology drug development.

"This is a significant milestone in the development of what we hope will be the first macrophage-targeting immunotherapy for patients with aggressive myeloid leukemias," said Dr. Markku Jalkanen, Chief Executive Officer of Faron. "The emerging *bexmarilimab* data from the Phase 1 part of the study have been very encouraging, showing continued efficacy signals and long duration of responses. We believe that *bexmarilimab* has the potential to improve patient outcomes and improve quality of life for those suffering from MDS, addressing the longstanding unmet medical needs in conditions which have had no new effective treatments in decades."

Faron recently reported updated, positive data from the Phase 1 part of the BEXMAB trial. Bexmarilimab produced a 50% remission rate in doublet dose cohorts (11 out of 22 patients.) Eight out of 11 patients achieved complete remission in the bone marrow with or without blood count recovery. The highest overall response rate (ORR) of 80% was observed among the previously failed HMA MDS group (4 out of 5 patients). The *bexmarilimab* / SoC combination continues to be well-tolerated at all tested dose levels with no dose-limiting toxicities. Faron expects to open additional sites in the U.S. and Europe to keep up with the increased recruitment speed.

For more information on BEXMAB, please visit ClinicalTrials.gov and reference identifier NCT05428969.

For more information on Project Optimus, visit https://www.fda.gov/about-fda/oncology-center-excellence/project-optimus

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

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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 BEXMAB

The BEXMAB study is a 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 i*n combination with SoC (azacitidine) treatment and to identify the recommended Phase II dose. 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 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 targeting myeloid cell function. *Bexmarilimab* is being investigated in Phase 1/2 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.