Faron Pharmaceuticals Ltd.

("Faron" or the "Company")

Inside Information: Additional Positive Data from the Phase 1 Part of the BEXMAB Study in Both Higher-Risk HMA-Failed MDS and r/r AML

Company announcement, 18 March 2024 at 7:00 a.m. GMT / 9:00 a.m. EET

Key highlights

- Latest readout of the BEXMAB study shows more responding patients and good durability of remission amongst HR HMA-failed MDS patients.
- 4/5 of the initial Phase 1 HR HMA-failed MDS patients were still alive after eight months of follow-up.
- While data do not yet allow the precise estimation of median overall survival, the survival benefit seen with the current follow-up already for these 5 first patients is very encouraging. This compares favorably to what has been seen with contemporary comparators.
- 3 additional HMA-failed HR MDS patients have been enrolled in Phase 1 part, leading to a total of 7 out of 8 patients responding, an overall response rate of 87.5%.
- Faron will be hosting a virtual webinar to discuss the additional data tomorrow, Tuesday, 19 March at 11.00 EET/9am GMT.

TURKU, Finland / BOSTON, Massachusetts – 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 provided further data from patients treated during the Phase 1 part of the ongoing BEXMAB trial that has moved into Phase 2 for higher-risk (HR) myelodysplastic syndrome (MDS) patients failed on previous hypomethylating agent (HMA).

Previous BEXMAB study results indicated a high overall response rate (ORR) of 5/5 amongst HR HMA-failed MDS patients, for whom there is no approved treatment. The majority of the initial Phase 1 patients have now been on treatment with *bexmarilimab* together with azacitidine for more than six months, and only one patient has been lost due to transformation of their HR MDS into acute myeloid leukemia (AML). Out of these initial 5 patients, 4 remain alive after eight months. Normally, patients with relapsed or refractory HR MDS have a median overall survival (mOS) of fewer than six months. The mOS of patients treated in the BEXMAB trial is not yet available but, based on the current data, it is estimated to be significantly higher than traditionally seen with current standard of care (or with current approved treatments).

After the already reported 5 HMA-failed HR MDS patients, 3 new HMA-failed HR MDS patients were enrolled, filling the remaining Phase 1 slots. Whilst it is too early to assess these patients for survival or durability, the previously seen high ORR has been corroborated with 2/3 responders. The third patient dropped out of the study early in cycle two due to an unrelated serious adverse event (SAE), bringing the current ORR to 7/8 patients (87.5%) in the HMA-failed HR MDS population. The best responses for these 8 patients are as follows: 1 complete response (CR), 3 marrow complete remissions (mCR), 1 partial response (PR), 2 hematological improvements, and 1 stable disease (SD) that dropped out early due to an unrelated SAE.

Mika Kontro, MD, PhD, Associate Professor at the Helsinki University Hospital Comprehensive Cancer Center and Principal Investigator of the BEXMAB trial, said: "We are continuing to see encouraging data from the BEXMAB trial with usually unresponsive patients going into remission after treatment with *bexmarilimab* and azacitidine. Whilst we don't have median overall survival rates yet, it is encouraging to see that some patients are alive and, importantly, enjoying a good quality of life even up to 12+ months after treatment initiation. I continue to be very excited about the potential of *bexmarilimab* to considerably improve outcomes for patients suffering from these aggressive conditions."

Dr. Markku Jalkanen, Chief Executive Officer of Faron, said: “These data are really remarkable and confirm our belief that we may finally have a treatment for this underserved patient population. The data are strongly supportive that a registrational trial would be positive against any contemporary comparator when the final endpoint is survival. We eagerly await completion of the Phase 2 part of the BEXMAB study so we can take these data to the FDA as soon as possible.”

For the 5 frontline HR MDS patients with 100% ORR previously reported at the American Society of Hematology (ASH) Annual Meeting last year, mOS has also not yet been reached. For the r/r AML patient cohort reported at ASH, which is bigger in size (n= 18) and more mature in follow-up (median follow-up six months), the mOS is currently estimated to be over 8 months (still subject to change as some patients are still ongoing). The historical mOS for this population is around six months, which means that the current data would support running a registrational trial with mOS also as the endpoint in this population.

Faron will be hosting a virtual webinar to discuss these data tomorrow, Tuesday, 19 March, at 11.00 EET/9am GMT.

There will be an opportunity to ask questions during the webcast. To register for the event visit: https://faron.videosync.fi/bexmab-study-update/ or contact the IR team for more information at investor.relations@faron.com.

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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.