Faron Pharmaceuticals Ltd.

("Faron" or the "Company")

Inside Information: Faron Reports Initial Positive Phase 2 Read-out in HMA-resistant MDS

Company announcement, Inside Information, 20 May 2024 at 7:00 a.m. BST / 9:00 a.m. EEST

Key highlights

- Initial preliminary phase 2 read-out from the BEXMAB Trial confirms earlier positive Phase 1 findings in MDS patients with prior HMA failure
- In Phases 1 & 2, 14 MDS patients who are refractory or relapsed on HMA (r/r MDS) and have no effective treatment options, show an objective response rate (ORR) of 79%
- The BEXMAB Phase 1 MDS patients with prior HMA failure are experiencing an estimated median overall survival (mOS) of approximately 13 months currently, compared to the 5-6 months that would typically be expected under standard of care historically

TURKU, Finland – Faron Pharmaceuticals Ltd. (AIM: FARN, First North: FARON), a clinical-stage biopharmaceutical company pursuing a CLEVER-1 receptor targeting approach to reprogramming myeloid cells to activate anti-tumor immunity in hematological and solid tumor microenvironments, today provided first data from patients treated during the Phase 2 part of the ongoing BEXMAB trial in myelodysplastic syndrome (MDS) patients that have failed a hypomethylating agent (HMA), also known as relapsed/refractory MDS (r/r MDS). There are limited viable treatment options for r/r MDS and the mOS for these patients is only 5.6 months historically (Prebet et al. 2011).

The BEXMAB Phase 1 results have already indicated a high overall response rate (ORR) of 87.5% (7/8) amongst HMA-failed MDS patients treated with a combination of *bexmarilimab* + azacitidine. There are now a total of 14 HMA-failed MDS patients treated in both Phase 1 & 2 with this novel combination. The treatment has been well tolerated, without any dose-limiting toxicity. The ORR in this otherwise untreatable population is 79% (11/14). The current true remission rate is 64% (9/14). Similar size patient cohorts treated with existing alternatives have reported 0-20% ORR, without deep and durable remissions.

The best responses for these 14 patients are as follows: 1 complete response (CR), 7 marrow complete remissions (mCR), 1 partial response (PR), 2 hematological improvements, 2 stable diseases (SD) and 1 progressive disease (PD). Two patients have moved on to receive bone marrow transplantation for a possibility of curative treatment. This is seldom seen in this population because patients usually cannot be brought to remission. For Phase 1 patients with adequate follow-up available the estimated mOS is currently 13.4 months, but still subject to change.

Dr. Amer Zeidan, Associate Professor of Medicine, Chief of Hematologic Malignancies Division, Director of Hematology Early Therapeutics Research, and leader of the clinical program and the Clinical Research Team for Leukemia and Myeloid Malignancies at Yale Cancer Center, who is also a leading investigator on the trial, said: "Management of patients with higher risk MDS after HMA failure is very challenging and with very limited options, and is currently considered one of the most urgent unmet clinical needs in MDS. *Bexmarilimab* is a promising agent that works by modulating the immune system and in early data from the ongoing clinical trial in MDS appears to have a very good safety profile and promising clinical activity, especially in median survival after HMA failure. While these are early data and in a small number of patients, if these findings continue to hold up, they would position *bexmarilimab* to potentially fill a very important clinical gap in the management of MDS patients".

Dr. Juho Jalkanen, Chief Executive Officer of Faron, said: "This is a significant milestone for Faron. Many of us have recognized the grave need for new treatment options in r/r MDS. With these first results from the Phase 2

continuing the positive results already seen in Phase 1, we are committed to rapidly advancing Bexmarilimab to market, because patients are waiting for treatment options like this".

Faron will be hosting a virtual webinar to discuss these data the day after tomorrow, Wednesday, May 22nd, at 17.00 EEST/15.00 BST

To register for the event visit: https://faron.videosync.fi/bexmab-study-update-may2024 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.