

Faron Pharmaceuticals Ltd.

("Faron" or the "Company")

Inside information: Faron Presents Phase 1 Data from BEXMAB in Myeloid Malignancies Trial at the 65th American Society of Hematology (ASH) Annual Meeting

- *Significant overall Response Rate (ORR) achieved in both HR-MDS (5/5) and HMA-failed MDS (5/5) patients*
- *The vast majority of responses are deep and durable with 7/10 MDS patients achieving CR/mCR and one additional patient transferred to stem cell transplantation*

Company Announcement, Inside Information

TURKU, Finland / BOSTON, Massachusetts - December 11, 2023 - Faron Pharmaceuticals Ltd. (AIM: FARN, First North: FARON), a clinical-stage biopharmaceutical company pioneering macrophage reprogramming for effective anticancer immunotherapies, today announced very positive Phase 1 data from the ongoing BEXMAB study in myeloid malignancies, being presented at the 65th American Society of Hematology (ASH) Annual Meeting & Exposition taking place until tomorrow, December 12, 2023, in San Diego, California, and virtually.

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 standard of care in patients with aggressive myeloid leukemias.

"The BEXMAB results continue to improve over time showing remarkable overall response rate in both higher-risk frontline as well as hypomethylating agent (HMA)-failed myelodysplastic syndrome (MDS) patients," said Dr. Markku Jalkanen, Chief Executive Officer of Faron. "The combination is well-tolerated and generates strong and durable leukemic blast eradication and immune responses. This solidifies *bexmarilimab*'s unique and leading mechanism of action in the field of myeloid cell reprogramming. With this compelling evidence we are well positioned to advance to the Phase 2 part of the [BEXMAB study](#) and actively pursue further regulatory interactions to navigate and refine the pivotal pathway for BLA filing".

Dr. Naval Daver, MD, Professor of Leukemia at The University of Texas MD Anderson Cancer Center and site Principal Investigator of the BEXMAB trial commented: "Addressing MDS poses a considerable therapeutic challenge given the limited efficacy of the current standard of care resulting in relatively low response rate and poor overall survival, especially in TP53 mutated and HMA-failed MDS patient populations. The data presented at ASH are promising, demonstrating a higher ORR and prolonged response duration in this trial compared to published historical benchmarks. These findings underscore the future potential of this combination in advancing the treatment of higher-risk and HMA-failed MDS."

Poster highlights include:

- Significant overall response rate observed in both previously HMA-failed (5 out of 5) and higher-risk MDS patient (5 out of 5) populations
- Observed responses were primarily deep and durable with 7/10 MDS patients achieving CR/mCR, and two demonstrating PR, out of which one moved on to receive a stem cell transplantation and one hematological improvement without remission (HI-P)
- The majority of higher-risk MDS patients were also TP53 mutated, typically associated with poor responsiveness to standard therapy, however all of them achieved CR/mCR upon receiving the treatment
- Clinical activity with 13/28 (48%) objective responses observed across all the indications, including r/r AML, and dose levels tested
- The combination of bexmarilimab and azacitidine remains well tolerated with immune-related adverse events observed at higher dose levels
- Clever-1 target engagement was confirmed in the bone marrow of treated patients together with an increased antigen presentation capacity and increased numbers of CD8 T and NK cells in patients

Poster presentation details:

Title: Encouraging Efficacy Observed in BEXMAB Study: A Phase 1/2 Study to Assess Safety and Efficacy of Bexmarilimab in Combination with Standard of Care in Myeloid Malignancies

Session Date and Time: Sunday, December 10, 2023, 6:00 PM - 8:00 PM PST

Session Title: Acute Myeloid Leukemias: Investigational Therapies, Excluding Transplantation and Cellular Immunotherapies: Poster II

Location: San Diego Convention Center, Halls G-H

Lead Authors: Mika Kontro, Helsinki University Hospital and University of Helsinki and Naval Daver, The University of Texas MD Anderson Cancer Center

Abstract Number: 2915

For more information on ASH poster, please visit www.faron.com

For more information on BEXMAB, please visit ClinicalTrials.gov and reference Identifier 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 targeting 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 treatments and as a monotherapy in last line solid cancers. 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.