

Faron Pharmaceuticals Ltd.

("Faron" or the "Company")

Inside information: Faron Announces Positive BEXMAB Study Update in Relapsed/Refractory AML and HMA-Refractory MDS Patients

- *Bexmarilimab* produces a 50% remission rate in doublet dose cohorts (11 out of 22 patients)
- Eight of the 11 patients are Complete Responders (CR) or CR with incomplete blood recovery (CRi)
- Highest overall response rate (ORR) of 80% observed in prior HMA-failure MDS group (4 out of 5 patients)
- *Bexmarilimab* continues to be well-tolerated with no dose-limiting toxicity observed
- Company to host virtual investor call to discuss data, today at 8:00 am EST

Company announcement, Inside Information

TURKU, Finland / BOSTON, Massachusetts – October 11, 2023 - Faron Pharmaceuticals Ltd. (AIM: FARN, First North: FARON), a clinical-stage biopharmaceutical company pioneering macrophage reprogramming for effective anticancer immunotherapies, today announces updated data from the Phase 1/2 BEXMAB study investigating *bexmarilimab* in combination with standard of care (SoC) in relapsed/refractory (r/r) acute myeloid leukemia (AML) and myelodysplastic syndromes (MDS) patients having failed hypomethylating agents (HMAs).

The updated data are consistent with the high objective response rate observed in the previous results. The most recent data includes read outs from a total of 22 patients (r/r AML with 12 patients, MDS frontline and MDS HMA-failed patients with five patients each) who have completed at least two or more treatment cycles. Eight of 11 patients achieved complete remission in the bone marrow with or without blood count recovery.

The highest single indication-specific ORR was observed among HMA-failed MDS patients (4 out of 5 patients; 80%). The combined study ORR continues to be high (11 out of 22 patients; 50%) across all patient groups having received two or more treatment cycles in the doublet. In most patients (75%), blast reduction was observed. A total of 29 patients have been recruited into the doublet cohort as of October 5, 2023.

Bexmarilimab continues to be well-tolerated at all tested dose levels as no dose-limiting toxicity has been observed. A total of 18 drug-related events were observed with the majority below Grade 3. Five drug-related events were reported as Grade 3 and above, including immune-related events (capillary leak syndrome, hemophagocytic lymphohistiocytosis and cryptogenic organizing pneumonia), as well as one event of increased liver enzymes.

"The emerging data from Phase 1/2 continue to be extremely promising, showing continued good safety, encouraging efficacy and long durations of response," said Dr. Markku Jalkanen, Chief Executive Officer of Faron. "These results strongly support the planned next step of beginning enrollment of the Phase 2 part of the BEXMAB study."

Dr. Jalkanen continued: “We believe that *bexmarilimab* has the potential to provide better patient outcomes and improve the quality of life of those suffering from relapsed/refractory AML and MDS, which are conditions with dire prognosis and limited new therapies in the last decades.”

Faron plans to initiate the Phase 2 part of the BEXMAB study in HMA-failed MDS and r/r AML patients in Q4 2023. Consistent with the FDA’s Project Optimus initiative, the planned Phase 2 will start with dose optimization and is expected to enroll 28-32 patients randomized between two selected doses. Faron plans to increase the number of US clinical sites from two to five sites to accelerate study recruitment. For more information on BEXMAB, please visit [ClinicalTrials.gov](https://clinicaltrials.gov) and reference Identifier NCT05428969.

Faron will host a virtual call for investors to discuss the data today at 08.00 EST/13.00 BST/15.00 EEST. There will also be an opportunity to ask questions during the webcast. To register for the webcast, please visit: <https://faron.videosync.fi/recent-bexmab-results-and-future-outlook-event> or contact the IR team for more information at investor.relations@faron.com.

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 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 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 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.