

**Faron Pharmaceuticals Ltd.**

("Faron" or "the Company")

**Inside Information: Faron Updates Positive Clinical Data from Phase I/II BEXMAB Study of  
*Bexmarilimab* in Relapsed/Refractory AML and MDS  
BEXMAB Study Update**

- Three of five patients in the 6 mg/kg *bexmarilimab* + azacitidine doublet cohort achieved objective responses (CR and mCR)
- Eight of 15 objective responses observed in all three doublet dosing cohorts
- One patient has stayed on treatment for 13 months
- Updated BEXMAB data supports advancement to Phase II in H2 2023 focusing on SoC relapsed/refractory AML and MDS patients failing hypomethylating agents (HMA)
- Filing of first Biologics License Application (BLA) to FDA planned for H1 2025
- Company management team will host a conference call and webcast to discuss the data today at 8:30 am ET

*Company Announcement, July 19, 2023*

*Inside Information*

TURKU, Finland / BOSTON, Massachusetts – Faron Pharmaceuticals Ltd. (AIM: FARN, First North: FARON), a clinical-stage biopharmaceutical company focused on tackling cancers via novel immunotherapies, today announces new positive clinical data from the Company's ongoing Phase I/II BEXMAB study.

The BEXMAB study (ClinicalTrials.gov: NCT05428969) investigates *bexmarilimab*, Faron's wholly owned immunotherapy asset, in combination with standard of care (SoC) in the aggressive hematological malignancies of relapsed/refractory (r/r) acute myeloid leukemia (AML) and myelodysplastic syndromes (MDS). The data reported here builds on earlier positive results presented on June 9, 2023 at the European Hematology Association (EHA) 2023 Hybrid Congress.

**BEXMAB Phase I Study Update:**

- Three of five patients in 6 mg/kg *bexmarilimab* + azacitidine doublet dosing cohort showed an objective response (OR) of complete remission of blasts in the bone marrow (mCR).
- In the three out of five patients in the 6 mg/kg + azacitidine doublet cohort, one patient also achieved a complete recovery of blood counts (CR).
- Eight of 15 ORs were observed across all three doublet dosing cohorts.
- Four of the eight patients across the three doublet dosing cohorts (1, 3 and 6 mg/kg) failed SoC hypomethylating agents (HMAs).
- All three patients with MDS and prior HMA failure demonstrated ORs (partial response (PR), mCR and CR) across dosing cohorts.
- Four patients out of six in the triplet dosing cohort treated with azacitidine, venetoclax and *bexmarilimab* have shown objective response.

"We are extremely encouraged by the continued efficacy signals of *bexmarilimab* and the long duration of the responses seen so far," said Dr. Mika Kontro, Associate Professor, Helsinki University

Hospital Comprehensive Cancer Center and Principal Investigator of the BEXMAB trial. “Our goal is to offer a unique hope for patients with no other treatment options in this late stage of AML and MDS.”

Faron plans to seek FDA advice during the Q3 2023. It also expects to advance to the Phase II part of BEXMAB in the H2 2023 in patients who are refractory to SoC in AML and have failed HMAs in MDS.

“The data indicates *bexmarilimab* has the strong potential to tackle an unmet medical need in relapsed/refractory AML and MDS,” said Chief Medical Officer Dr. Marie-Louise Fjällskog. “We’re excited to advance *bexmarilimab* as a leading agent in the fight against cancer and look forward to generating further supporting data ahead of an anticipated BLA filing in H1 2025.”

### **Conference Call and Webcast**

The Company’s management team will host a conference call and webcast with investors and analysts to discuss the data later this morning on **Wednesday, July 19, 2023, at 8:30 am ET**. The live call may be accessed by dialing (877) 407-3982 for callers in the US and (201) 493-6780 for international callers and entering the conference ID: 13740209. The live webcast presentation with accompanying slides will be accessible [here](#) and on the Investor Relations Calendar page of the Company’s website at [www.faron.com/investors/calendar](http://www.faron.com/investors/calendar). Following the completion of the event, a replay will be available on the Company’s website.

**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 first-in-human, open-label Phase I/II 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](http://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.