# FARON

#### Faron Pharmaceuticals Ltd.

("Faron" or the "Company")

## Detailed Analysis of BEXMAB Data Provides Insights into Patient Profiles of Responding HMA-Failed MDS Population

#### **Company Announcement**

**TURKU, Finland / BOSTON, Massachusetts – January 25, 2024** – 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 details from its further analysis of data from the completed Phase 1 part of the ongoing BEXMAB trial.

Patients are currently being enrolled in the Phase 2 of the BEXMAB trial, which is evaluating the safety and efficacy of investigational immunotherapy *bexmarilimab* at two dose levels (Project Optimus part), in combination with standard of care (SoC), in patients with hypomethylating agents (HMAs)-refractory or -relapsed myelodysplastic syndrome (MDS), an aggressive myeloid leukemia with very few treatment options.

The new analysis of data from the Phase 1 part of the trial explores the 100% overall response rate (ORR) achieved among both the higher-risk frontline and HMA-failed MDS patients treated with a bexmarilimab/azacitidine combination – 5 out of 5 patients in each population – and examines previous therapies in the patients' treatment pathways.

In the HMA-failed MDS patient group:

- Patients had been previously treated with azacitidine monotherapy or combinations of up to four therapies that included azacitidine or decitabine + magrolimab, venetoclax and sabatolimab
- 3 of the 5 patients were refractory to previous HMA-therapy, with progressive disease (PD) or stable disease (SD) being the best responses achieved from that therapy
- 2 out of the 5 patients had relapsed after treatment with azacitidine or an azacitidine/venetoclax combination

"This analysis shows the deep and durable responses that can be achieved with *bexmarilimab* in combination with standard of care, in MDS patients who are refractory to HMA therapy or who have relapsed on HMA therapy or HMA/venetoclax combination therapy," said Dr. Markku Jalkanen, Chief Executive Officer of Faron. "Patients with high-risk MDS who have failed HMA therapy face a poor prognosis and median overall survival in refractory MDS is just 4-6 months with no viable treatment options. Yet here we have data showing that patients are surpassing anticipated survival rates and maintaining remission. It is remarkable to see patients going into remission with *bexmarilimab*/azacitidine after showing disease progression on all the leading azacitidine combinations such as venetoclax, sabatolimab and magrolimab. These are highly significant findings that provide us with continued confidence in the potential of *bexmarilimab* to provide better patient outcomes and improve the quality of life of those suffering from these aggressive conditions."

An updated corporate deck now contains these data and is available on the Company's website.

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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

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.