

Faron Pharmaceuticals Oy

("Faron" or the "Company")

Inside Information: Encouraging Additional Data for *Bexmarilimab* for the Treatment of Hematological Malignancies

BEXMAB Study Update

- Two objective responses (ORR) and two stable disease (SD) patients, with one having > 50% reduction of blast cells, observed in the second doublet cohort
- Of the three patients with ORR in the first doublet cohort, two remain on the study after 10 and 9 months, respectively, and the third has undergone a potentially curative transplantation
- Second dose level in doublet well-tolerated and third cohort open for enrolment
- First dose level in triplet well tolerated and second cohort open for enrollment
- Plans to initiate the study's Phase II in H2 2023

Company announcement, April 17, 2023

Inside information

TURKU, FINLAND / BOSTON, MA - Faron Pharmaceuticals Oy (AIM: FARN, First North: FARON), a clinical stage biopharmaceutical company focused on tackling cancers via novel immunotherapies, today announces additional positive data from the Company's Phase I/II BEXMAB study. BEXMAB is investigating *bexmarilimab*, Faron's wholly owned immunotherapy asset, in combination with standard of care (SoC) in relapsed/refractory acute myeloid leukemia (AML) and myelodysplastic syndromes (MDS).

The responses from these patients are further defined as:

- In the second doublet cohort (3mg/kg + azacytidine), two patients have objective responses thus far, including one complete response with incomplete blood count recovery (CRi) and one patient with hematological improvement in platelets (HI-P). There are two patients with SD, of which one has > 50% reduction in bone marrow blasts, and one patient with progressive disease.
- The first doublet cohort (1mg/kg + azacytidine) has seen a complete response with incomplete hematological recovery (CRi) in a patient with relapsed/refractory AML. The patient is still responding after 10 months. Another patient with MDS that experienced CR is still in remission after 9 months. An additional patient that achieved a partial response has undergone a possibly curative allogenic stem cell transplantation.
- No *bexmarilimab*-related Grade 3 or higher adverse events (AEs) or serious adverse events (SAEs) observed in the second dosing cohort and enrolment into the third cohort (6mg/kg) ongoing.
- The first triplet cohort (1mg/kg + azacytidine + venetoclax) was well-tolerated and the second cohort (3mg/kg + azacytidine + venetoclax) has opened for enrollment.
- Additional efficacy read-outs for all cohorts expected in the upcoming months.
- On a potential path to a Biologics License Application (BLA) submission, the Company plans to seek FDA advice during Q3 2023.

“We are extremely encouraged by the continued efficacy of *bexmarilimab* and the long duration of the responses seen so far,” said Chief Medical Officer Marie-Louise Fjällskog. Dr. Fjällskog noted the success of the MDS patient who did not respond to previous azacytidine therapy, but with the addition of *bexmarilimab*, the patient is undergoing potentially curative transplantation.

The primary objective of the BEXMAB study (ClinicalTrials.gov: NCT05428969) is to determine the safety and tolerability of *bexmarilimab* in combination with SoC (azacytidine and venetoclax) treatment and to identify the recommended Phase II dose. Secondary objectives include characterizing preliminary efficacy as well as *bexmarilimab*'s pharmacokinetic profile in combination with SoC treatment and assessing its immunogenicity.

In January 2023, the Company announced objective responses in 3 out of 5 patients dosed in the first doublet cohort of the BEXMAB study. The Company also announced enrollment updates for the study's cohorts, and that it had opened the first triplet cohort with *bexmarilimab*, azacytidine and venetoclax in newly diagnosed AML patients who are unable to tolerate chemotherapy.

“The latest data are a powerful indication of the therapeutic potential for *bexmarilimab* in hematological malignancies,” said CEO Dr. Markku Jalkanen.

This announcement contains inside information for the purposes of Article 7 of Regulation (EU) No 596/2014 ("MAR").

For more information please contact:

Media Contact

Faron Pharmaceuticals

Jennifer C. Smith-Parker
Head of Communications
Jennifer.Smith-Parker@faron.com

Investor Contact

Faron Pharmaceuticals

Julia Balanova
VP, Investor Relations
julia.balanova@faron.com
investor.relations@faron.com
Phone: +1 (917) 306-6096

Cairn Financial Advisers LLP, Nomad

Sandy Jamieson, Jo Turner
Phone: +44 (0) 207 213 0880

Peel Hunt LLP, Broker

Christopher Golden, James Steel
Phone: +44 (0) 20 7418 8900

Sisu Partners Oy, Certified Adviser on Nasdaq First North

Juha Karttunen

Phone: +358 (0)40 555 4727

Jukka Järvelä

Phone: +358 (0)50 553 8990

Consilium Strategic Communications

David Daley, Lindsey Neville, Namrata Taak

faron@consilium-comms.com

Phone: +44 (0)20 3709 5700

About *Bexmarilimab*

Bexmarilimab is Faron's wholly owned, investigational immunotherapy with the potential to provide immune stimulation for treatment-resistant cancers through targeting myeloid cell function. A novel anti-CLEVER-1 humanized antibody, *bexmarilimab* targets CLEVER-1 positive (Common Lymphatic Endothelial and Vascular Endothelial Receptor 1) tumor-associated macrophages (TAMs) in the tumor microenvironment, converting highly immunosuppressive M2 macrophages to immune-stimulating M1 macrophages. As an immuno-oncology therapy, *bexmarilimab* has therapeutic potential in combination with other standard treatments including immune checkpoint molecules in both solid tumors and hematologic malignancies.

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 (azacytidine) 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 Oy

Faron Pharmaceuticals Oy (AIM: FARN, First North: FARON), together with its subsidiaries, is a clinical stage biopharmaceutical group focused on building the future of immunotherapy by harnessing the power of the immune system to tackle cancer. *Bexmarilimab*, a novel anti-CLEVER-1 humanized antibody, is its investigational immunotherapy 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 and solid cancers in combination with other standard treatments including immune checkpoint molecules. Faron is headquartered in Turku, Finland. 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.