

Faron Announces New Biomarker Data from Phase I/II BEXMAB Study at EHA2023 Hybrid Congress

- *Bexmarilimab* mode of action in AML/MDS supported with durable Clever-1 target engagement in bone marrow, with increases observed in T and NK cells and antigen presentation
- Clinical activity across indications, with objective responses in 5 of 10 patients
- Dose escalation ongoing, with initiation in 2H 2023 of Phase II in relapsed/refractory AML and MDS after failure on hypomethylating agents

Press Release, June 9, 2023

TURKU, FINLAND / BOSTON, MA – Faron Pharmaceuticals Oy (AIM: FARN, First North: FARON), a clinical-stage biopharmaceutical company focused on tackling cancers via novel immunotherapies, announces the release of new biomarker data from the ongoing Phase I/II BEXMAB study of *bexmarilimab* in combination with standard of care (SoC) in the aggressive hematological malignancies of acute myeloid leukemia (AML) and myelodysplastic syndrome (MDS).

The data will feature in a poster presentation at the European Hematology Association (EHA) 2023 Hybrid Congress on June 9, 2023.

In BEXMAB patients, a high Clever-1 expression in leukemic blasts is associated with lower levels of antigen presentation. The proposed mode of action of *bexmarilimab* in AML/MDS is now supported by the biomarker data, which suggests durable Clever-1 target engagement in the bone marrow tumor microenvironment with increases observed in key cell types limiting cancer growth and spread, namely T and NK cells (up to 2-3-fold). In addition, *bexmarilimab* treatment increased HLA-DR expression by leukemic blasts, indicating improved immune recognition and eradication of the malignant cells.

The poster also updates preliminary efficacy data, previously communicated by the Company in [January](#) and [April](#) 2023, showing objective responses in 5 out of 10 patients across the first and second dose cohorts of the study (1 or 3mg/kg *bexmarilimab* + azacitidine), as observed by a reduction in bone marrow blasts, leading to complete and partial remissions. The initial data also shows that *bexmarilimab* treatment is well-tolerated without adding toxicity to standard azacitidine therapy.

"The BEXMAB study continues to generate data that are an excellent indication of the therapeutic potential of *bexmarilimab* to change the treatment paradigm for patients with hematological malignancies," said Marie-Louise Fjällskog, M.D., Ph.D., Chief Medical Officer of Faron Pharmaceuticals. "We are encouraged by the results and look forward to progressing the BEXMAB program."

Presentation Details:

Title:

A PHASE I/II STUDY TO ASSESS SAFETY, TOLERABILITY AND PRELIMINARY EFFICACY OF BEXMARILIMAB IN COMBINATION WITH STANDARD OF CARE AZACITIDINE (DOUBLET) IN

Poster ID:

P542

Date/Time:

June 9, 2023 at 6pm EST

The poster is available on Faron's website at <https://www.faron.com/investors/most-recent-presentations>.

Investor contacts:**US, Faron Pharmaceuticals**

Julia Balanova

VP, Investor Relations

julia.balanova@faron.com

Phone: +1 (917) 306-6096

EUR, Faron Pharmaceuticals

Yrjö Wichmann

VP, Investor Relations

yrjo.wichmann@faron.com

Phone: +358 (0)40 5868 979

Media Contact**Faron Pharmaceuticals**

Jennifer C. Smith-Parker

Head of Communications

Jennifer.Smith-Parker@faron.com**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 Nort

Juha Karttunen

Phone: +358 (0)40 555 4727

Jukka Järvelä

Phone: +358 (0)50 553 8990

Consilium Strategic Communications

David Daley, Lindsey Neville

faron@consilium-comms.com

Phone: +44 (0)20 3709 5700

About *Bexmarilimab*

Bexmarilimab, a humanized IgG4 monoclonal antibody, binds common lymphatic endothelial and vascular endothelial receptor-1 (Clever-1), a novel macrophage checkpoint. Clever-1 alters the function of macrophages, a type of white blood cell that surrounds and kills micro-organisms. High Clever-1 expression is associated with therapeutic resistance and poor outcomes. Ex vivo treatment of AML bone marrow cells with *bexmarilimab* alone or in combination with azacitidine/venetoclax increases antigen presentation, induces secretion of proinflammatory cytokines (signaling proteins that help control inflammation in the body) and increases activation of white blood cells called T cells, which allows cancer to be targeted and eliminated.

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 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 cancers in combination with other standard treatments including immune checkpoint molecules, and as a monotherapy for untreatable solid tumors. 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. 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.