Faron Pharmaceuticals Oy

("Faron" or **"Company")**

Inside Information: *Deepening Response of Bexmarilimab in Combination with SoC in Hematological Malignancies*

BEXMAB Study Update

- Partial responder becomes complete responder with complete remission of blasts in blood and bone marrow followed by normalization of blood counts
- Second patient demonstrated a partial response
- Stable disease observed in the other treated patients
- Two patients enrolled in second cohort with increased *bexmarilimab* dose with azacitidine
- Enrolment initiated in the triplet cohort combining *bexmarilimab* with azacitidine and venetoclax

Company announcement, December 5, 2022 at 02:00 AM (EST) / 07:00 AM (GMT) / 09:00 AM (EET)

Inside information

TURKU, FINLAND / BOSTON, MA – Faron Pharmaceuticals Oy (AIM: FARN, First North: FARON), a clinical stage biopharmaceutical company focused on tackling difficult-to-treat cancers and inflammation via precision immunotherapy, today announces a further update on the Company's Phase I/II BEXMAB study, investigating *bexmarilimab*, Faron's wholly owned precision immunotherapy asset, in combination with standard of care (SoC) in multiple hematological malignancies.

In this latest update from the ongoing, open-label clinical trial, the Company reports that:

- An azacytidine-refractory acute myeloid leukemia (AML) patient with partial responses as communicated on October 31, 2022, achieved a complete remission, with incomplete blood cell count recovery after four treatment cycles. This was followed by full blood count recovery after five treatment cycles.
- The second patient, recently diagnosed with myelodysplastic syndrome (MDS), showed early signs of efficacy, with reduced blast counts. This pattern is similar to the first patient and as such the patient could be considered a partial responder.
- The remaining patients of the first cohort have reported stable disease (SD) status.
- *Bexmarilimab* continues to be well-tolerated with no dose-limiting toxicities or safety concerns observed in the five patients receiving 1mg/kg weekly dosing together with azacitidine.
- Study expansion to major hematological US centers is ongoing.

The primary objective of the BEXMAB study is to determine the safety and tolerability of *bexmarilimab* in combination with SoC (azacitidine and venetoclax) treatment and to identify the recommended Phase II dose. Secondary objectives include characterizing *bexmarilimab*'*s* pharmacokinetic profile in combination with SoC treatment and assessing its immunogenicity. The initial treatment efficacy is followed by measuring cancer cell blast number in blood and bone marrow.

The BEXMAB study has opened the second predefined weekly dosing level of 3mg/kg and the start of dosing in the new triplet cohort combining *bexmarilimab* with azacitidine and venetoclax.

"We continue to be encouraged by the promising early data observed in this trial, notably the patients who have already shown control of blast counts in blood and bone marrow," said Dr. Marie-Louise Fjällskog, M.D., Ph.D., Chief Medical Officer of Faron. "These observations support the potential for synergy of *bexmarilimab* in combination with standard of care. In addition, patient recruitment has started in the first-line triplet therapy

with *bexmarilimab*, azacitidine and venetoclax in newly diagnosed acute myeloid leukemia patients deemed unsuitable for conventional chemotherapy. "

This and other earlier data will be shared with the current BEXMAB study group and potential new US study site investigators who will convene for the 64th American Society for Hematology (ASH) meeting in New Orleans, Louisiana from December 10-13, 2022.

Further details of the BEXMAB study are available on ClinicalTrials.gov (Identifier: NCT05428969).

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, investigative precision immunotherapy with the potential to provide permanent immune stimulation for difficult-to-treat cancers through targeting myeloid cell function. A novel anti-Clever-1 humanised antibody, *bexmarilimab*targets Clever-1 positive (Common Lymphatic Endothelial and Vascular Endothelial Receptor 1) tumour associated macrophages (TAMs) in the tumour microenvironment, converting these highly immunosuppressive M2 macrophages to immune stimulating M1 macrophages. As an immuno-oncology therapy, *bexmarilimab* has potential as a single-agent therapy or in combination with other standard treatments including immune checkpoint molecules in both solid tumors and hematologic malignancies. Beyond immuno-oncology, it offers potential in infectious diseases, vaccine development and more.

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 aggressive hematological malignancies including 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. Based on initial safety data, there is potential for expansion to include a first line triplet therapy of *bexmarilimab*, azacitidine and venetoclax in newly diagnosed AML patients who are not able to tolerate chemotherapy. Clever-1 is highly expressed in both AML and MDS and associated with therapy resistance,

limited T cell activation and poor outcomes. Directly targeting Clever-1 could limit the replication capacity of cancer cells, increase antigen presentation, ignite an immune response, and allow current chemotherapy treatments to be more effective.

About Faron Pharmaceuticals Ltd.

Faron (AIM: FARN, First North: FARON) is a clinical stage biopharmaceutical company developing novel treatments for medical conditions with significant unmet needs caused by dysfunction of our immune system. The Company currently has a pipeline based on the receptors involved in regulation of immune response in oncology, organ damage and bone marrow regeneration. *Bexmarilimab*, a novel anti-Clever-1 humanized antibody, is its investigative precision immunotherapy with the potential to provide permanent immune stimulation for difficult-to-treat cancers through targeting myeloid function. Currently in Phase I/II clinical development as a potential therapy for patients with solid tumors and hematologic malignancies, *bexmarilimab* has potential as a single-agent therapy or in combination with other standard treatments including immune checkpoint molecules. Traumakine is an investigational intravenous (IV) interferon beta-1a therapy for the treatment of acute respiratory distress syndrome (ARDS) and other ischemic or hyperinflammatory conditions. Traumakine is currently being evaluated by the 59th Medical Wing of the US Air Force and the US Department of Defense for the prevention of multiple organ dysfunction syndrome (MODS) after ischemia-reperfusion injury caused by a major trauma. Faron is based 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 particular, the early data from initial patients in the MATINS trial may not be replicated in larger patient numbers and the outcome of clinical trials may not be favourable or clinical trials over and above those currently planned may be required before the Company is able to apply for marketing approval for a product. In addition, other factors which could cause actual results to differ materially include the ability of the Company to successfully licence its programmes 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.