Faron Pharmaceuticals Oy
("Faron" or **"Company")**

Inside Information: Promising start to a new study investigating bexmarilimab for the treatment of hematological malignancies – BEXMAB Study Update

- Dose escalation to the second predefined level in first clinical study to investigate *bexmarilimab* in hematological malignancies
- No dose-limiting toxicities or safety concerns observed among five patients to have received initial dose at 1 mg/kg every week
- Early signs of efficacy with partial response observed in one patient after three dosing cycles
- New triplet cohort to be opened combining *bexmarilimab* with azacitidine and venetoclax
- Good target coverage as shown by reduced Clever-1 levels in patients' blood and bone marrow aspirates

Company announcement, October 31, 2022 at 03:00 AM (EDT) / 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 that dosing has moved to the second level in the Company's Phase I/II BEXMAB study. BEXMAB is investigating *bexmarilimab*, Faron's wholly-owned precision immunotherapy asset, in combination with standard of care (SoC) in multiple hematological malignancies.

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 first stage of the BEXMAB study comprises four predefined dose levels commencing at *bexmarilimab* 1mg/kg. Following the announcement of patient dosing commencement in June 2022, five patients have received 1mg/kg weekly dosing of *bexmarilimab* with no dose-limiting toxicities or safety concerns observed. These data warrant escalation of dosing with *bexmarilimab* to the second predefined weekly dosing level of 3mg/kg.

All first stage cohort patients are alive. The longest treated patient at three cycles has revealed partial response as observed by reduced cancer activity with reduced blast (cancer cell) counts and normalised blood cell counts.

Initial data from patients dosed with *bexmarilimab* also show a significant reduction in levels of soluble Clever-1 protein in the blood of treated patients. Earlier research from the Company's MATINS study, investigating the safety and efficacy of *bexmarilimab* monotherapy in solid tumor cohorts, indicates that this soluble form of the Clever-1 protein is a direct inhibitor of T cells and could have an immunosuppressive effect in all locations of the body, therefore decreasing the general immune capacity of patients. This initial finding will be followed in all patients throughout the BEXMAB study.

"The escalation of dosing with *bexmarilimab* to the second level in the BEXMAB study, following confirmation of no dose limiting toxicities, is an encouraging early signal as we pursue this immunotherapy's potential to treat hematological malignancies in the combination setting," said Marie-Louise Fjällskog, M.D., Ph.D., Chief Medical Officer of Faron. "We have also observed an early indicator of clinical benefit in the first patient dosed, alongside the observation of a reduction in levels of immunosuppressive soluble Clever-1 protein in the blood of treated patients. We look forward to generating further data as the trial progresses to help determine the optimal dose of *bexmarilimab* to take forward into Phase II."

"The safety findings in the trial's first five patients, showing no dose-limiting toxicities or safety concerns with the 1mg/kg weekly dosing of *bexmarilimab*, is a very encouraging step supporting the scientific rationale to combine *bexmarilimab* and azacitidine with the aim to activate an immune response to control the disease," said Mika Kontro, M.D., Ph.D., Helsinki University Hospital Comprehensive Cancer and Principal Investigator of the BEXMAB trial. "The initial safety data that we gather will inform the potential for expansion into a Phase II study in combination with azacitidine. The study may now also progress to include first-line triplet therapy with *bexmarilimab*, azacitidine and venetoclax in newly diagnosed acute myeloid leukemia patients not benefitting from conventional chemotherapy."

"The BEXMAB study is off to a great start, and we are eagerly waiting to see the first data from the triplet therapy, where *bexmarilimab* could become a cornerstone of first-line treatment in newly diagnosed AML patients," said CEO Markku Jalkanen. "We wish to thank our investigators, and especially patients, for the wonderful start of this trial, and their commitment in helping to find new treatments for this grave condition."

"For investors these are very encouraging - though early - results. We should remember that AML is an extremely serious indication with over 90% mortality in five years and all new approaches that can change this are urgently needed," said Yrjö Wichmann, Faron's VP Funding and IR. "Earlier we were able to show clinical benefit in solid tumor cancers and now we have positive indication also in blood cancers, in which the Clever-1 target molecule is expressed directly on the surface of the cancer cells themselves. Additionally, as AML is a very serious condition, the route to regulatory approval can be faster if results are exceptional."

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

Faron will also host a special event in December where further details of the BEXMAB study will be presented together with current treatment practices for hematological malignancies.

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 myelodysplatic 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.