Faron Pharmaceuticals Ltd.
("Faron" or "Company")

Faron Announces US Food and Drug Administration and Finnish Medicines Agency Approval to Initiate Phase I/II *Bexmarilimab* Combination Study in Hematologic Malignancies

- *Phase 1 dose escalation study will evaluate the safety and tolerability of combination therapy and determine the recommended dose for Phase 2 expansion*
- *Patient recruitment will commence in the coming weeks*
- *Supporting pre-clinical* bexmarilimab *hematology data was presented at recent European Hematology Association 2022 Congress*

Company Announcement, May 16, 2022 at 09:00 AM (EEST) / 07:00 AM (BST) / 2:00 AM (EDT)

TURKU, FINLAND / BOSTON, MA – Faron Pharmaceuticals Ltd. (AIM: FARN, First North: FARON), a clinical stage biopharmaceutical company focused on building the future of immunotherapy by harnessing the power of the immune system to tackle cancer and inflammation, today announces that both the U.S. Food and Drug Administration (FDA) and Finnish Medicines Agency (FIMEA) have cleared Faron's Investigational New Drug (IND) application to begin the Company sponsored BEXMAB study. BEXMAB is a novel Phase I/II study to assess safety, tolerability and preliminary efficacy of *bexmarilimab*, Faron's wholly-owned investigational precision cancer immunotherapy, in combination with standard of care (SoC) therapy in patients with relapsed acute myeloid leukemia (AML), myelodysplastic syndrome (MDS), or chronic myelomonocytic leukemia (CML). This marks the first time *bexmarilimab* will be assessed as part of a clinical study in hematologic malignancies.

"We are pleased that our IND application was cleared to proceed, and we can further explore the strong scientific rationale for combining *bexmarilimab* and *azacitidine*." said Marie-Louise Fjällskog, M.D., Ph.D., Chief Medical Officer of Faron. "Research has shown a clear survival benefit among certain blood cancer patients with low Clever-1 expression, a receptor known to be expressed on immunosuppressive macrophages in the tumor microenvironment. By adding *bexmarilimab* to standard of care we expect to downregulate Clever-1 expression, thereby increasing antigen presentation and allowing the immune system to better identify and kill cancer cells."

The primary objective of the BEXMAB study is to determine the safety and tolerability of *bexmarilimab* in combination with SoC treatment and to identify the recommended Phase 2 dose. Secondary objectives include characterizing the pharmacokinetic profile of *bexmarilimab* in combination with SoC treatment (*azacitidine*) and to assess the immunogenicity of *bexmarilimab*. Based on initial safety data, there is potential for Phase II expansion and to include a first line triplet therapy of *bexmarilimab*, *azacitidine* and *venetoclax* in newly diagnosed AML patients who are not able to tolerate chemotherapy. Patient recruitment is expected to begin in the coming weeks.

"We know from pre-clinical research, some of which was presented recently at EHA, that certain blood cancer cells, especially with myeloid background, carry significant amounts of cell surface Clever-1," said Dr. Markku Jalkanen, Chief Executive Officer of Faron. "This corresponds with the presence of considerable amounts of soluble Clever-1, which limits T cell activation leading to a possible systemic loss of immune capacity. Directly targeting Clever-1 could ignite the immune system, limit the replication capacity of cancer cells, and allow current chemotherapy treatments to be more effective."

In addition to the BEXMAB study focused on hematologic malignancies, Faron is also investigating *bexmarilimab* in solid tumors. The ongoing Phase I/II MATINS clinical trial is assessing *bexmarilimab* as a potential monotherapy in late-stage, heavily pre-treated patients across multiple tumor types. Additionally, the Company expects to initiate a trial assessing the safety and tolerability of *bexmarilimab* in combination with an approved anti-PD-1 molecule in multiple solid tumors later this year.

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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. In mouse models, *bexmarilimab* has successfully blocked or silenced Clever-1, activating antigen presentation and promoting interferon gamma secretion by leukocytes. Additional pre-clinical studies have proven that Clever-1, encoded by the Stabilin-1 or STAB-1 gene, is a major source of T cell exhaustion and involved in cancer growth and spread. Observations from clinical studies to date indicate that Clever-1 has the capacity to control T cell activation directly, suggesting that the inactivation of Clever-1 as an immune suppressive molecule could be more broadly applicable and more important than previously thought. As an immuno-oncology therapy, *bexmarilimab* has potential as a single-agent therapy or in combination with other standard treatments including immune checkpoint molecules. Beyond immuno-oncology, it offers potential in infectious diseases, vaccine development and more.

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 untreatable solid tumors, *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 in global trials as a potential treatment for hospitalized patients with COVID-19 and with 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.