Faron Pharmaceuticals Ltd.
("Faron or Company")

Faron Pharmaceuticals Presents Results from PD-1 Blockade Refractory Melanoma Cohort of MATINS Trial at 19th International Congress of The Society for Melanoma Research

- 100% overall survival at 12-months in PD-1 blockade refractory melanoma patients who experienced clinical benefit from *bexmarilimab*
- Patients with cold tumors, defined by low baseline levels of pro-inflammatory cytokines, were more likely to experience clinical benefit following treatment with *bexmarilimab*
- Patients who experienced clinical benefit from *bexmarilimab* had a seven-fold increase in serum interferon gamma (IFNγ), suggesting retreatment with anti-PD-1 could be beneficial

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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 results from the melanoma cohort in the ongoing phase I/II MATINS (Macrophage Antibody to Inhibit Immune Suppression) trial, will be presented at the 19th International Congress of The Society for Melanoma Research, being held in Edinburgh, Scotland, October 17-20, 2022.

The melanoma cohort is one of the ten advanced treatment-resistant solid tumor types included in the MATINS study investigating the potential of *bexmarilimab*, Faron's wholly owned investigational precision cancer immunotherapy, as a monotherapy. *Bexmarilimab* targets CLEVER-1 positive (Common Lymphatic Endothelial and Vascular Endothelial Receptor 1) on immune suppressive tumor associated macrophages. Around 50% of the tumor mass is made up of tumor associated macrophages, limiting the efficacy of currently approved cancer immunotherapies, including PD-1 blockade.

Within melanoma, anti-PD-1-based therapy failure occurs in 50-60% of advanced melanoma patients due to primary resistance. Additionally, 40% of patients who initially respond develop acquired resistance[1]. *Bexmarilimab* reinvigorates exhausted T-cells and converts immune suppressive macrophages into immunostimulatory macrophages, thus, converting cold tumors to hot tumors and creating an environment where retreatment with anti-PD-1 therapies may be successful.

Data from 22 melanoma patients will be presented at the congress. All patients had failed prior checkpoint inhibition and were treated with *bexmarilimab* monotherapy at varying doses. The median number of previous treatment lines was three and the median age of patients was 60.

- Of the 22 subjects, five patients (23%) experienced clinical benefit during therapy.

- Among patients who had 12-month follow-up completed, 100% (3/3) of patients who experienced clinical benefit were alive compared to 11% (1/9) of patients who did not experience clinical benefit.

- Median overall survival (OS) was 457 days for patients who experienced clinical benefit compared to 189 days for patients who did not experience clinical benefit. This represents a 2.4-fold increase in OS for patients with clinical benefit.

- Mean baseline IFNγ levels among patients experiencing clinical benefit was one-fourth of the mean value of patients who did not experience clinical benefit. Mean levels among these patients increased significantly and remained elevated over the course of a three-weekly treatment, indicating an immune response was activated and that the tumor was converted from cold to hot.
    - Mean increase from baseline among patients who experienced clinical benefit:
        - A three-fold increase at 8 days
        - A seven-fold increase at 15 days
        - A five-fold increase at 22 days

- Receiver operating characteristic curves found that low levels of both IFNγ and TNFα was highly predictive of clinical benefit (AUC 0.87, 95% CI 0.71 to 1.00)

- Higher intratumoral CLEVER-1 levels at baseline were observed among patients experiencing clinical benefit and could become an essential component of future studies to build accompanying diagnostic tool for patient selection

"Checkpoint inhibitors have transformed the treatment of metastatic melanoma, but far too many patients are not benefiting from currently approved immunotherapies," said Dr. Anna Minchom, Consultant Medical Oncologist at the Royal Marsden Hospital, Team Leader at the Institute of Cancer Research and MATINS investigator. "The biomarker analysis in this trial of *bexmarilimab* is very interesting, indicating immune activation and pointing the way for combining *bexmarilimab* with other immunotherapies."

"These data, together with our biomarker analysis, reinforce *bexmarilimab's* unique proposition – its capacity to ignite immunity in heavily pre-treated, last line cancer patients who either failed on or were ineligible for treatment with currently approved immunotherapy drugs," said Marie-Louise Fjällskog, M.D., Ph.D., Chief Medical Officer of Faron. "Our development program exploring the potential of *bexmarilimab* across solid tumors and hematologic malignancies, both as a monotherapy and in combination with standard of care therapies, seeks to further explore this novel immunotherapy's potential as a catalyst for the immune system."

References

1. Mooradian, M. J. and Sullivan, R. J. (2019) What to do when anti-PD-1 therapy fails in Patients with Melanoma. **Oncology**. 33 (4) 141-8

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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 in both solid tumors and hematologic malignancies. Beyond immuno-oncology, it offers potential in infectious diseases, vaccine development and more.

About MATINS

The MATINS (Macrophage Antibody To INhibit immune Suppression) study is a first-in-human open label phase I/II clinical trial investigating the tolerability, safety and efficacy of *bexmarilimab* in ten different hard-to-treat metastatic or inoperable solid tumour cohorts - cholangiocarcinoma, colorectal cancer, cutaneous melanoma, ER+ breast cancer, gastric cancer, hepatocellular carcinoma, ovarian cancer, uveal melanoma, pancreatic cancer and anaplastic thyroid carcinoma - which are all known to host a significant number of CLEVER-1 positive tumour-associated macrophages (TAMs). The completed Part I of the trial dealt with tolerability, safety and dose escalation. The ongoing Part II is focused on identifying patients who show an increased number of CLEVER-1 positive TAMs and exploring safety and efficacy. Part III will be focused on assessing efficacy. Data from MATINS have shown that bexmarilimab has the potential to be the first macrophage immune checkpoint therapy. To date, the investigational therapy has been shown to be safe and well-tolerated, making it a low-risk candidate for combination with existing cancer therapies, and has demonstrated early signs of clinical benefit in patients who have exhausted all other treatment options.

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.