Faron Pharmaceuticals Ltd
("Faron or Company")

Faron Pharmaceuticals Announces Top-Line Data on *Bexmarilimab* Dose Variation from MATINS Advanced Solid Tumor Patients

- *Bexmarilimab* was well tolerated in patients receiving higher dose levels or frequency of administration
- Treatment induced significant systemic interferon (IFN) gamma increase - again showing the capacity of *bexmarilimab* to activate immune response in cancer patients, especially in patients with immunologically "cold" tumors
- Higher baseline Clever-1 levels in the tumors was associated with increased clinical benefit and could become an essential component as a diagnostic tool for patient selection
- Median overall survival based on patients from Part I and II (n=138) was 14.9 months for patients who benefited from treatment with *bexmarilimab* compared to 4.4 months for those who did not, representing a 3.4-fold increase
- Clinical benefit was observed across all dosing regimens
- New data, together with recent scientific advisory board recommendations and pharmacokinetic modelling, allow Faron to file the end of Phase I/II package with the US Food and Drug Administration later this year
- Company to host *Bexmarilimab* Development Update webcast today, Tuesday, September 20, at 02:00 pm EEST, 12:00 pm BST, 7:00 am EST

Company Announcement, September 20, 2022 at 02:00 AM (EST) / 07:00 AM (BST) / 09:00 AM (EEST)

Insider information

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 further dose escalation data from its Phase I/II MATINS (Macrophage Antibody To INhibit immune Suppression) study investigating the safety and efficacy of *bexmarilimab* monotherapy in ten different hard-to-treat metastatic or inoperable solid tumor cohorts. The latest progress with the MATINS study was focused on higher dose levels and frequencies to finalize the dose for future study designs as a single agent or in combination with other anti-cancer treatments, including PD-1 blocking agents. Higher doses, up to 30mg/kg, were well tolerated as was more frequent dosing of 1-3 mg/kg administered every week to every other week.

Despite the relatively rapid clearance of *bexmarilimab* from circulation, the majority of evaluated dosing regimens produced significant Clever-1 occupancy in circulating monocytes and reduced the presence of soluble Clever-1 in blood. This data suggests that *bexmarilimab* dosing can be effective across several dosing regimens. Currently, the highest clinical benefit (25-30% of the test cohort) was observed at 1 mg/kg and seen with weekly and three-weekly administration. Additional pharmacokinetic / pharmacodynamic (PK/PD) and clinical efficacy data is expected shortly and should together with pharmacokinetic modelling enable Faron to present an acceptable data package to the US Food and Drug Administration (FDA) for determination of the recommended dosing regimen(s) for future studies.

As previously reported, low IFN-gamma levels predict clinical benefit as measured by extended overall survival (Part I data). Additionally, Part II patients with low baseline IFN-gamma levels experienced a five-fold increase IFN-gamma levels in their blood, which was not seen in patients with high baseline IFN-gamma levels. The regression analysis of this correlation was highly significant (p=0.007) and indicates that *bexmarilimab* has the capacity to ignite immunity in heavily pre-treated, last line cancer patients who either did not respond to or were ineligible for treatment with currently approved immunotherapy drugs.

The data also showed that the lower the pre-existing IFN-gamma response is, the higher the IFN-gamma levels will increase with *bexmarilimab* treatment. This highlights the importance of the patient phenotype that benefits from *bexmarilimab*, i.e., the characteristics of the tumor are critical when determining whether a patient is likely to benefit from treatment, making a biomarker strategy extremely important for the future development of *bexmarilimab*. The key tumor characteristics have now been clearly identified and Faron is well placed to drive a biomarker strategy forward to guide patient selection.

"Bringing the promise of immunotherapy to more cancer patients starts with the ability to identify which patients are likely to benefit from specific treatments," said Dr. Markku Jalkanen, Chief Executive Officer of Faron. "We now have a clear understanding of which patients benefit from *bexmarilimab* treatment and can identify them using a validated staining antibody, which can be widely accessible and adapted to routine practice. In addition, we have blood-based cytokine profiles to support our biological approach, and even further strengthen our biomarker development strategy."

An updated survival analysis including 138 patients from Part I and Part II of the MATINS trial showed median overall survival was 14.9 months for patients who benefited from treatment with *bexmarilimab* compared to 4.4 months for those who did not, representing a 3.4-fold increase. This corresponds to a hazard ratio estimated using a Cox model of 0.33 (95% confidence interval from 0.18 to 0.61).

The Company plans to compile the end of Phase I/II package, which will include additional PK/PD and clinical efficacy data, and file it with the FDA to obtain regulatory advice for further clinical development of *bexmarilimab*, as a stand-alone last line treatment and in earlier line combinations.

”The fact that *bexmarilimab* treatement was well tolerated at all dosing levels and frequencies is significant,” said Petri Bono, MD, PhD., Chief Medical Officer, Terveystalo Finland and Principal Investigator of the MATINS trial. “One of the big challenges we have seen with immuno-therapy drugs to date, particularly when used in combination, is dose limiting toxicity. *Bexmarilimab’s* safety profile in a monotherapy setting suggests combination therapy with an anti-PD-1 would also be well tolerated.”

“We have made steady progress with our MATINS trial and following a detailed evaluation of this latest data, expect to submit a full data package to the FDA and request an end of Phase I/II meeting,” said Marie-Louise Fjällskog, M.D., Ph.D., Chief Medical Officer of Faron. “We look forward to sharing all of our MATINS data, including the updated dosing and survival data, with the FDA and discussing the best possible way to bring this new treatment option forward to patients.”

Faron thanks the patients and investigators who are participating in the MATINS clinical trial and SAB members for their advice.

To register for the *Bexmarilimab* Development Update webcast on September 20, 2002, please visit: https://faron.videosync.fi/2022-bexmarilimab-development-update.

A Finnish language interview with Dr. Markku Jalkanen covering the important information shared during the event will also take place on September 20, 2022. A link to a recording of this interview will be made available on the "Investors" section on Faron's website at: https://www.faron.com/investors.

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. 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.