



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

## Faron Presents Results from Melanoma Cohort of MATINS Trial at 18<sup>th</sup> Congress of the European Association of Dermato-Oncology (EADO)

- *Compelling 30% clinical benefit rate seen following treatment with bexmarilimab in heavily pre-treated, checkpoint inhibitor refractory patient population*
- *Analysis estimates 100% overall survival at 12-months for patients who experienced clinical benefit following treatment with bexmarilimab*
- *Biomarker analysis shows melanoma patients with low baseline levels of inflammatory cytokines in blood and high Clever-1 positivity in tumor are more likely to benefit from treatment with bexmarilimab and experience significant increases in serum interferon gamma (INFy) during treatment*

Press release, April 21, 2022 at 18:30 PM (EEST) / 16:30 PM (BST) / 11:30 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 results from the melanoma cohort in the ongoing phase I/II MATINS (Macrophage Antibody to Inhibit Immune Suppression) trial, will be presented at the 18th Congress of the European Association of Dermato-Oncology (EADO), being held in Seville, Spain, April 21 to April 23, 2022.

The melanoma cohort is one of the ten advanced treatment-resistant solid tumor types included in Part II (110 patients) of the MATINS study, which is investigating the potential of *bexmarilimab*, Faron's wholly-owned investigational precision cancer immunotherapy, as a monotherapy. *Bexmarilimab* targets tumor associated macrophages, which are known to be immunosuppressive, make up nearly 50% of the tumor mass, and limit the efficacy of currently approved cancer immunotherapies, including anti PD-1/L1. As previously communicated, melanoma is among five different tumor types from the original 10 studied to have shown the strongest clinical benefit rate (CBR = partial response or stable disease) – 30% – alongside gastric cancer (30%), cholangiocarcinoma (30%), hepatocellular carcinoma (40%) and breast cancer (40%), following treatment with *bexmarilimab*.

Data from 11 melanoma patients (including the full cohort of 10 patients in Part II and one additional patient with same dosing regimen from Part I) who were refractory to checkpoint inhibition are being presented at the congress. All patients were treated with 1mg/kg of *bexmarilimab* monotherapy, every three weeks. The median number of previous treatment lines was three, the median age of patients was 60.

- Of the 11 patients, four experienced clinical benefit – one patient had a partial response after two cycles of *bexmarilimab* (tumor growth reduced by 40% from baseline) but was discontinued before a confirmatory scan was performed. Three patients had stable disease (i.e., clinical benefit rate of 30% in Part II).
- Current estimates for 12-month survival in Part II melanoma cohort were 100% for the patients who experienced clinical benefit following treatment compared to 33.3% of non-CBR patients.
- A preliminary biomarker analysis including the melanoma cohort showed that patients with higher intra-tumoral Clever-1 positivity and low baseline levels of serum interferon gamma (IFNy) and tumor necrosis factor alpha were more likely to experience clinical benefit following treatment with *bexmarilimab*. Among those patients who experienced clinical benefit, a marked rise in serum IFNy levels was seen during treatment. IFNy is a necessary pro-inflammatory cytokine for response to checkpoint inhibitors like PD-1/L1, highlighting *bexmarilimab's* combination potential.

"This rate of clinical benefit is particularly striking when you consider these are heavily pre-treated patients, all of whom were refractory to currently approved checkpoint inhibitor therapy," said Marie-Louise Fjällskog, M.D., Ph.D., Chief Medical Officer of Faron. "*Bexmarilimab's* ability to ignite an immune response in these patients means that it may serve as a catalyst for the immune system allowing initially checkpoint inhibitor resistant patients to become responsive to PD-1/L1 blockade."

"Additionally, the biomarker analysis among melanoma patients is consistent with our broader analyses and suggests that two cytokines, which can be measured by a standard blood test as part of a patient's routine care, could hold the key to understanding

which patients will gain the greatest benefit from this novel immunotherapy. Knowing which patients are most likely to respond to treatment is key to both the development process and the successful roll out of new therapeutic approaches.”

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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 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-Cleaver-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](http://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.