

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

***Bexmarilimab* monotherapy shows promising anti-tumour activity in multiple advanced solid tumours**

- Headline data reported from patients enrolled in completed Part I and ongoing Part II of MATINS study
- Strongest disease control rate (DCR) of 31% seen in cutaneous melanoma, gastric cancer and cholangiocarcinoma patients
- 100% six-month survival rate observed in DCR patients compared with 31.1 % for non-DCR patients
 - Equivalent prior treatment durations for DCR and non-DCR patients suggests DCR with *bexmarilimab* is indicator of anti-tumour activity and survival benefit

Company announcement, 17 May 2021 at 9.00 AM (EET)

Inside information

TURKU – FINLAND – Faron Pharmaceuticals Oy (AIM: FARN, First North: FARON), the clinical stage biopharmaceutical company, today announces promising new data from its ongoing *bexmarilimab* MATINS study, reporting combined headline data from 141 evaluable patients enrolled in the completed Part I and ongoing Part II of the study.

The open label Phase I/II MATINS clinical trial is investigating the safety and preliminary efficacy of *bexmarilimab*, Faron's wholly-owned novel precision cancer immunotherapy targeting Clever-1, a receptor known to be expressed on immunosuppressive macrophages in the tumour microenvironment. In this trial *bexmarilimab* is being investigated as a potential monotherapy in patients with solid tumours who have exhausted all treatment options.

As previously communicated, the first expansion stage (Part II) of the study has progressed significantly with strong patient recruitment across the 10 different hard-to-treat solid tumours under investigation – cholangiocarcinoma, colorectal cancer, cutaneous melanoma, ER+ breast cancer, gastric cancer, hepatocellular carcinoma, ovarian cancer, uveal melanoma, pancreatic cancer and anaplastic thyroid carcinoma. The latest data, as of the end of April, include results from 141 patients enrolled in the completed Part I (n=30) and ongoing Part II (n=111) of the study. Patients were dosed at five different levels (0.1, 0.3, 1.0, 3.0 and 10 mg/kg) and received one to 12 doses (median, three doses) of *bexmarilimab* every three weeks. Median follow-up was 2.1 months (range, 0.3 to 8.2 months).

Key Findings

- Across the 141 evaluable patients, median progression-free survival (PFS) was 59 days (95% confidence interval, 57 – 60) and median overall survival (OS) was 129 days (95% confidence interval, 115 – 178).

- Per RECIST 1.1 criteria, the DCR (partial response + stable disease rate) among responding patients was 11.4 % at cycle four of treatment across all ten solid tumour types.
- Among responding patients, OS and PFS were improved (hazard ratio for OS 0.19; CI 0.06-0.60 and hazard ratio for PFS 0.09; CI 0.04-0.23, respectively). This improved survival in responding patients was not associated with duration of previous therapy. Six-month survival rate was 100% for DCR patients compared to 31.1 % for non-DCR patients.
- Strongest results were observed in cutaneous melanoma (3/9 patients), gastric cancer (3/10 patients) and cholangiocarcinoma (3/10 patients) resulting in a 31.0 % DCR.
- Most common treatment emergent adverse events (TEAEs) were fatigue (25% of patients), abdominal pain (24%) and anaemia (20%) and only 10 out of the total 145 recorded serious TEAEs (14.1% of all TEAEs) were considered related to the study drug.

Dr. Markku Jalkanen, Faron's CEO, said: “*Bexmarilimab*’s ability to increase survival in patients who have exhausted all treatment options is significant and demonstrates the importance of targeting myeloid cell control in the development of next generation immunotherapies. *Bexmarilimab* is designed to switch immunosuppressive macrophages in the tumour microenvironment to become immune stimulating and we believe its unique mechanism of action offers broad potential across a range of hard-to-treat cancers.

“These data demonstrate strong initial safety and tolerability, and promising anti-tumour activity in several refractory metastatic solid tumours – cutaneous melanoma, gastric cancer and cholangiocarcinoma – which helps us to determine in which cancer cohorts *bexmarilimab* offers the most promise. Together with the additional work underway investigating higher and more frequent dosing, biomarkers of efficacy and the potential for combination with earlier lines of therapy, we are building a clear path towards the next stage of the study.”

Further detailed analysis of the data will be presented at an upcoming scientific congress.

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. 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 Oy

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 humanised 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 tumours, *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 hospitalised 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.

Caution regarding 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.