



Faron Pharmaceuticals Ltd.  
("Faron")

**Faron Announces Presentation of Updated MATINS Data at ESMO Showing *Bexmarilimab* Delivers Compelling Antitumour Activity Across Five Different Advanced Solid Tumors**

- Strongest disease control rate (DCR) observed in five different tumor types – cutaneous melanoma (30%), gastric cancer (30%), cholangiocarcinoma (30%), hepatocellular carcinoma (40%) and breast cancer (40%) patients
- Landmark analysis estimates overall survival at six months for DCR (partial response + stable disease rate) patients at 83% compared to 29% for non-DCR patients
- Treatment with macrophage-targeting *bexmarilimab* was well tolerated with only 7% of treatment related adverse events reported as grade three or four and 0% reported as grade five
- Company to host webinar to discuss updated MATINS data on September 21, 2021 at 8.30 am EDT / 13.30 pm BST / 15.30 pm EEST

Company announcement, September 17, 2021 at 02:00 AM (EDT) / 07:00 AM (BST) / 09:00 AM (EEST)

**Inside 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 announced updated results from the Phase I/II MATINS (Macrophage Antibody To INhibit immune Suppression) study investigating the safety and efficacy of *bexmarilimab*. The data will be featured in a Proffered Paper session today at the European Society for Medical Oncology (ESMO) 2021 Congress (Late Breaking Abstract Presentation #38, Friday, September 17, 2021; 7:30 am EDT / 12:30 pm BST / 2:30 pm EEST).

The updated results from the MATINS study include patients from Part I (30 patients) and Part II (110 patients) of the trial. Current estimate for median progression free survival for all these patients was 59 days (95% confidence interval, 58-61). Estimated median overall survival (OS) for all patients was 151 days (95% confidence interval, 118 – 190).

Landmark OS analysis of Part I/II patients who received three courses of treatment and had their scheduled tumor imaging at cycle four (n=91) estimated that 83% of patients achieving disease control rate (DCR) status were alive at six months after the landmark (approximately 240 days from initiation of treatment) compared to 29% of non-DCR patients. The most significant disease control rate (DCR) among Part II cohorts was observed in cutaneous melanoma (30%), gastric cancer (30%), cholangiocarcinoma (30%), hepatocellular carcinoma (40%) and breast cancer (40%) patients.

"The updated MATINS data provide additional evidence that *bexmarilimab* is well tolerated and shows for the first time that clinical benefit is associated with long term survival in patients with late-stage solid tumors who have exhausted all standard treatment options," said Petri Bono, MD, PhD., Chief Medical Officer, Terveystalo Finland and Principal Investigator of the MATINS trial. "The efficacy and survival data are particularly compelling when you consider the late-stage, treatment-refractory disease patient population and inclusion of nonimmunogenic cold tumors in the trial."

The open label Phase I/II MATINS clinical trial is investigating the safety and 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 tumor microenvironment. In the MATINS trial *bexmarilimab* is being investigated as a potential monotherapy in patients with solid tumors who have exhausted all other treatment options.

The first expansion stage (Part II) of the study enrolled patients across 10 different hard-to-treat solid tumors – cholangiocarcinoma, colorectal cancer, cutaneous melanoma, ER+ breast cancer, gastric cancer, hepatocellular carcinoma, ovarian cancer, uveal melanoma, pancreatic cancer and anaplastic thyroid carcinoma. Investigator assessed confirmed disease control rate per RECIST 1.1 at cycle four was 17% across completed part II cohorts. Treatment with *bexmarilimab* was well tolerated with only 7% of treatment related adverse events (TRAEs) reported as grade three or four and 0% reported as grade five. Additionally, none of the TEAEs resulted in a decrease or modification of dosing. The most common TRAEs were fatigue, anemia, abdominal pain and decreased appetite.

"These updated data strengthen our belief that treatment with *bexmarilimab* can increase survival in patients with a variety of late stage solid tumors," said Dr. Markku Jalkanen, Chief Executive Officer of Faron. "We look forward to discussing these results with

the FDA and finalizing plans for the Part III expansion cohorts, which we hope to convert to pivotal stage development for a regulatory submission. Additionally, all biomarker data are currently being analyzed for potential patient selection purposes and we simultaneously continue to advance our plans to investigate *bexmarilimab* in additional clinical settings, including neoadjuvant therapy, in combination with checkpoint inhibitors and as a treatment for hematological malignancies.”

Faron will host a webinar to discuss the updated MATINS data on Tuesday, September 21, 2021 at 8.30 am EDT, 13.30 pm BST, 15.30 pm EEST. The webinar will feature a presentation by Jussi Koivunen, MD, PhD, Medical Director, Oncology at Faron, which will be followed by a live Q&A session. The event can be accessed at the "Investors" section on Faron's website at <https://www.faron.com/investors>. A replay will be made available on the investor section of Faron's website shortly after the event.

**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 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](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.