



Presentation of Biomarker Data at AACR 2022

Faron Pharmaceuticals Ltd

("Faron or Company")

Faron Announces Upcoming Presentation of Biomarker Analysis from Patients in MATINS Trial at AACR Annual Meeting 2022

- Analysis tested performance of baseline cytokine serum IFN γ and TNF α levels to identify patients that experienced disease control following *bexmarilimab* treatment compared to those that did not
- Patients with low baseline IFN γ and TNF α levels found to experience significantly higher clinical benefit following *bexmarilimab* treatment
- *Bexmarilimab*'s unique mode of action could serve as a catalyst for the immune system allowing initially checkpoint inhibitor resistant patients to become responsive to PD-1 blockade

Press Release, March 9, 2022 at 02:00 AM (EST) / 07:00 AM (GMT) / 09:00 AM (EET)

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 an analysis of biomarker data from patients treated with *bexmarilimab* as part of the ongoing phase I/II MATINS (Macrophage Antibody to Inhibit Immune Suppression) trial, will be presented at the upcoming American Association for Cancer Research (AACR) Annual Meeting being held in New Orleans, US, from April 8 – 13, 2022. These data (Abstract #2767) will be featured in the "Biomarkers Predictive of Therapeutic Benefit" session on Tuesday April 12, 2022 from 9:00 AM - 12:30 PM.

Top line data from the biomarker analysis, which was announced by the Company in December 2021, showed that patients with low baseline levels of serum interferon gamma (IFN γ) and tumor necrosis factor alpha (TNF α) were more likely to experience clinical benefit following treatment with *bexmarilimab*, Faron's wholly-owned investigational precision immunotherapy asset. Data scheduled for presentation at AACR includes more detailed analysis of 30 patients across three tumor types (advanced gastric cancer, cutaneous melanoma and cholangiocarcinoma) showing:

- Mean levels of IFN γ were 5.11 pg/ml (SD +/- 4.99 pg/ml) in patients who experienced a clinical benefit versus 13.07 pg/ml (SD, +/- 13.26) in patients who did not experience a clinical benefit with

bexmarilimab

- Mean levels of TNFa were 0.96 pg/ml (SD, +/- 0.74 pg/ml) in patients who experienced a clinical benefit versus 2.37 pg/ml (SD, +/- 1.43 pg/ml) in patients who did not experience a clinical benefit with *bexmarilimab*

The conclusion from the analysis is that, when used together, IFN γ and TNFa are highly predictive of response to *bexmarilimab* ($P < 0.0001$), and patients with low IFN γ and TNFa levels experienced significantly higher clinical benefit following treatment with *bexmarilimab*. Patients with low levels of pro-inflammatory cytokines experiencing higher clinical benefit is opposite to what is usually seen with currently approved checkpoint inhibitors and other T cell activating agents.

“Understanding which patients are most likely to benefit from immunotherapy treatment is key to tackling cancer,” said Petri Bono, MD, PhD., Chief Medical Officer, Terveystalo Finland and Principal Investigator of the MATINS trial. “This biomarker analysis shows that IFN γ and TNFa, which can both be measured by a standard blood test, perform well in identifying patients likely to respond to *bexmarilimab* and could offer the potential to personalize a patient’s therapy and, ultimately, improve their outcome. This is especially important in earlier treatment line settings and with combination regimens.”

“This analysis continues to strengthen our understanding of what happens in the tumor microenvironment when patients are treated with *bexmarilimab*,” said Dr. Markku Jalkanen, Chief Executive Officer of Faron. “It provides a strong biological rationale to guide our ambitious development program exploring *bexmarilimab*’s potential as a monotherapy and in combination with other therapies, only increasing our confidence of the potential impact this novel macrophage-targeting immunotherapy could have on cancer care. *Bexmarilimab*’s ability to ignite immune reaction could become a significant new tool to increase the stagnated response levels of the currently available and widely used anti-PD-(L)1 treatments.”

The ongoing 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. Landmark overall survival (OS) data presented at the Company’s R&D Day in February from patients in Part I/II of the trial who received three courses of treatment and had their scheduled tumor imaging at cycle four (n=92) estimated that 70% of disease control rate (DCR = partial response + stable disease rate) patients were alive at nine months after the landmark (that is, approximately 11 months from initiation of treatment) compared to 26% of non-DCR patients. The most DCR among Part II cohorts was observed in cutaneous melanoma (30%), gastric cancer (30%), cholangiocarcinoma (30%), hepatocellular carcinoma (40%) and breast cancer (40%) patients. Treatment with *bexmarilimab* continues to be well tolerated with no new safety signals reported and no treatment related adverse events resulting in a decrease or modification of dosing.

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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.

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.