



Faron Pharmaceuticals Ltd.
("Faron")

Topline Biomarker Analysis Shows *Bexmarilimab* Ignites Immune Response in Patient Population That Has Not Traditionally Benefited from Current Immunotherapy Treatments

- Patients with low baseline levels of inflammatory cytokines in blood achieved significantly higher clinical benefit following treatment with *bexmarilimab* monotherapy
- Low inflammatory biomarker profile is likely to predict *bexmarilimab* monotherapy clinical benefit
- Ignition of immune response, as indicated by increased levels of inflammatory cytokines following treatment with *bexmarilimab*, suggests patients could become responsive to PD-1 blockade

Company announcement, December 9, 2021 at 02:00 AM (EDT) / 07:00 AM (GMT) / 09:00 AM (EET)

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 announces topline biomarker data from the Phase I/II MATINS (Macrophage Antibody to Inhibit Immune Suppression) trial of *bexmarilimab*. The initial biomarker data shows patients with low interferon gamma (IFNg) and tumor necrosis factor alpha (TNFa) levels experienced significantly higher clinical benefit (defined as partial response or stable disease) following treatment with *bexmarilimab*. The biomarker analysis included the first three cohorts of special interest from the trial: cutaneous melanoma, gastric cancer, and cholangiocarcinoma.

Among the 30 patients included in the analysis, all of whom were heavily pre-treated, and PD-1 blockade refractory/resistant, nine experienced clinical benefit and 21 did not following treatment with *bexmarilimab* monotherapy. At baseline, the nine patients who experienced clinical benefit had significantly lower serum IFNg ($P = 0.03$) and TNFa ($P = 0.005$) levels compared to patients that did not experience clinical benefit. Additionally, a more than 100% increase in IFNg levels was seen after the first cycle of *bexmarilimab* treatment among patients who experienced clinical benefit.

"The biomarker analysis shows that in patients receiving treatment with *bexmarilimab*, interferon gamma levels increased after the first dose. Interferon gamma is a marker for inflammation which suggests *bexmarilimab* may amplify an immune response," said Dr. Anna Minchom, Consultant Medical Oncologist at the Royal Marsden Hospital, Team Leader at the Institute of Cancer Research and MATINS investigator. "There is urgent clinical need to identify potential treatment options for patients who do not, currently, respond to existing immunotherapy drugs."

TNFa and IFNg are measured by a standard blood test. The ability to have these classical pro-inflammatory cytokines measured as part of a patient's routine clinical care could expedite treatment decisions improving patient care, which today requires costly biopsies and pathology tests.

"The initial biomarker analysis is exciting as it helps us better understand which patients are most likely to respond to treatment with *bexmarilimab* monotherapy," said Dr. Markku Jalkanen, Chief Executive Officer of Faron. "The data also demonstrates that *bexmarilimab* is igniting an immune response, turning a cold tumor hot, in certain heavily pre-treated patients with checkpoint inhibitor resistant disease. This means *bexmarilimab* may serve as a catalyst for the immune system allowing initially checkpoint inhibitor resistant patients to become responsive to PD-1 blockade."

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. Overall survival data at six months was presented at the European Society for Medical Oncology (ESMO) 2021 Congress that showed that 83% of patients who experienced clinical benefit following treatment with *bexmarilimab* were alive at six months compared to 29% of patients who did not experience clinical benefit. Median survival for patients who experienced clinical benefit had not yet been reached. 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.

The company will complete a full evaluation of the biomarker data and share the detailed results at a future medical meeting.

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.

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.