

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

First-in-human *bexmarilimab* results published in Clinical Cancer Research

- Results reveal the role of Clever-1 receptor in suppressing adaptive immunity
- *Bexmarilimab*'s macrophage-targeting approach activates T-cells and drives anti-tumour immune responses in cold tumours that are not otherwise responsive to immunotherapy

Company announcement, 3 June 2021 at 9.00 AM (EET)

TURKU – FINLAND – Faron Pharmaceuticals Oy (AIM: FARN, First North: FARON), the clinical stage biopharmaceutical company, today announces the publication of research supporting the immunotherapeutic blockade of Clever-1 to activate anti-tumour immune responses in advanced cancer patients. The research, published in *Clinical Cancer Research*, a journal of the American Association for Cancer Research, analyzes the mode of action of *bexmarilimab*, both *in vitro* and in heavily pre-treated metastatic cancer patients from Part I (dose-finding) of Faron's ongoing Phase I/II MATINS study.

Bexmarilimab is Faron's wholly-owned novel precision cancer immunotherapy targeting Clever-1 (common lymphatic endothelial and vascular endothelial receptor 1), a receptor expressed on immunosuppressive macrophages in the tumour microenvironment. The humanised monoclonal antibody is currently being investigated as a potential monotherapy in patients with solid tumours who have exhausted all treatment options. The ongoing, open label Phase I/II multicenter MATINS study has treated more than 140 patients to date. A recent and previously communicated analysis of data from patients enrolled in the completed Part I and ongoing Part II of the study identified promising anti-tumour activity in multiple advanced solid tumours.

The research published in *Clinical Cancer Research* was conducted by Dr. Maija Hollmén and colleagues at the University of Turku, Finland – part of Faron's scientific network – and was supported by the investigators in the MATINS study. It explores the systemic immune signatures induced by *bexmarilimab* in advanced cancer patients with solid tumours and provides a mechanistic understanding of how a macrophage-targeted approach can promote robust activation of T-cells. In the cancer patients studied, it was found that administration of *bexmarilimab* successfully lowered the suppressive potential of macrophage precursors circulating in the blood. Treatment led to suppression of nuclear lipid signalling pathways and a proinflammatory phenotypic switch in blood monocytes. These effects were accompanied by a significant increase and activation of peripheral T-cells with indications of antitumour responses in some patients.

The researchers conclude that the therapeutic blockade of Clever-1 reveals a pathway linking the innate and adaptive immune system and that targeting macrophages can promote an immune switch, converting immunologically ignorant tumours to an immune activated state, supporting further exploration of Clever-1 as an immunotherapeutic drug target.

Commenting on the findings, Dr. Maija Hollmén, Turku University, Finland, said: “Macrophages have been proven to be critical in driving an immunosuppressive tumour microenvironment, which ultimately counteracts the effects of current T-cell targeting therapies. Successfully overcoming this suppression is critical to developing effective new cancer therapies. We have demonstrated through this research that adaptive immune activation can be achieved by modulating the behaviour of macrophages.

“The notable immunological finding from this research is that anti-Clever-1 treatment can induce robust peripheral T-cell activation in patients with advanced cancer. This systemic immune activation is a promising feature of the clinical anti-tumour activity of *bexmarilimab*.”

The research, entitled “Systemic blockade of Clever-1 elicits lymphocyte activation alongside checkpoint molecule downregulation in patients with solid tumors” can be accessed via the link below:

Link to the article: <https://clincancerres.aacrjournals.org/content/early/2021/06/01/1078-0432.CCR-20-4862>

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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.