

**Faron Announces Presentation of Biomarker Analysis at 2022 ASCO Annual Meeting Showing Promising Clinical Benefit of *Bexmarilimab* in Patients with Low PD-L1 and High Clever-1 Levels**

- *Biomarker analyses indicate that the tumors of patients benefitting from treatment with bexmarilimab had:*
  - *statistically significant higher levels of Clever-1 positive intra-tumoral cells*
  - *low PD-L1 levels, a population that does not typically respond to or is ineligible for treatment with currently approved checkpoint inhibitors*
- *Adds to growing research to identify optimum patient group for macrophage-targeting immunotherapy following earlier finding that patients with low serum IFN $\gamma$  and TNF $\alpha$  levels (immunologically cold tumors) were more likely to experience clinical benefit*
- *Combination studies underway in both solid tumors and hematologic malignancies to further explore the clinical benefit of Clever-1 inhibition and potential of bexmarilimab to prime the immune system in patients unresponsive to existing therapies*

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**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 new 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 Society of Clinical Oncology (ASCO) 2022 Annual Meeting being held in Chicago, US from June 3 – 7. These data (Abstract #2645) will be featured in the “Developmental Therapeutics—Immunotherapy” session on Sunday, June 5, 2022 at 9:00 AM EDT.

The MATINS trial is investigating the safety and efficacy of *bexmarilimab* as a monotherapy in patients with solid tumors who have exhausted all treatment options. Faron's wholly-owned novel precision cancer immunotherapy targets Clever-1, a receptor known to be expressed on immunosuppressive macrophages in the tumor microenvironment. *Bexmarilimab* works by converting highly immunosuppressive M2 macrophages to immune stimulating M1 macrophages, which activates antigen presentation and promotes interferon gamma secretion by leukocytes. This can turn “cold” tumors into “hot” tumors; allowing the immune system to recognize and target cancer cells.

The biomarker analysis shows that the tumors of patients benefitting from *bexmarilimab* treatment expressed low levels of PD-L1 – a patient group that generally does not receive benefit from or is ineligible for treatment with currently approved checkpoint inhibitors. Median PD-L1 Combined Positive Score (CPS) was 1 (range 0-2) in patients that benefitted from *bexmarilimab*. The PD-L1 CPS score was 5 (range 0-100) for patients who did not benefit from *bexmarilimab* treatment. Further, the analysis showed that patients with higher levels of Clever-1 positive intra-tumoral cells were more likely to experience a clinical benefit when treated with *bexmarilimab* [15% vs 3%, respectively;  $p=0.038$ ].

"While the arrival of currently available checkpoint inhibitors was, undoubtedly, one of the most exciting breakthroughs in cancer care, their low response rate in most tumor types continues to hinder their clinical application," said Petri Bono, MD, PhD., Chief Medical Officer, Terveystalo Finland and Principal Investigator of the MATINS trial. "There remains an urgent need for effective new treatment options, including novel assets that work synergistically with existing checkpoint inhibitors to ignite and amplify the patient's immune response."

These data build on Faron's continued research to identify the patient population most likely to benefit from *bexmarilimab* treatment and follow the Company's earlier findings, announced in December 2021, that patients with low baseline serum levels of serum interferon gamma (IFN $\gamma$ ) and tumor necrosis factor alpha (TNF $\alpha$ ) were more likely to experience clinical benefit following treatment with *bexmarilimab*. Those patients with immunologically cold tumors also exhibited an ignition of immune response, as indicated by increased levels of IFN $\gamma$  following therapy, which suggests *bexmarilimab* may serve as a catalyst for the immune system allowing initially checkpoint inhibitor resistant or ineligible patients to become responsive to PD-1 blockade.

"Using a validated staining technique, these preliminary biomarker analyses indicate that *bexmarilimab* treatment may benefit patients whose tumors express low levels of PD-L1 and higher levels of CLEVER-1 positive intra-tumoral cells, which is opposite to what is usually seen with checkpoint inhibitors and other T cell activating agents," said Marie-Louise Fjällskog, M.D., Ph.D., Chief

Medical Officer of Faron. “We are encouraged by this data as it furthers our belief that *bexmarilimab* has the potential to bring the promise of immunotherapy to a much broader patient population both as a monotherapy and in combination with currently approved anti-PD-1/L1 therapies.”

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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 in both solid tumors and hematologic malignancies. 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 solid tumors and hematologic malignancies, *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 by 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.