



Faron Pharmaceuticals Ltd.  
("Faron" or "Company")

### Ex Vivo Data Presented at EHA2022 Congress Suggest Critical Role for Clever-1 in Hematological Cancer Outcome and Drug Resistance

- *Clever-1 is expressed in patient bone marrow blasts and monocytes in acute myeloid leukemia (AML) and myelodysplastic syndrome (MDS), with the highest levels observed in M4/M5 subtypes with poor outcome*
- *Blocking Clever-1 with bexmarilimab in these patients induced immune activation as observed through increased antigen presenting molecule, human leucocyte antigen DR (HLA-DR) expression and declined PD-1 expression*
- *The combination of azacytidine with bexmarilimab augmented HLA-DR induction and overcame the HLA-DR suppressing effect of the bcl-2 inhibitor venetoclax*

Press release, May 12, 2022 at 17:50 PM (EEST) / 15:50 PM (BST) / 10:50 AM (EDT)

**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 preclinical data to support the Company's upcoming clinical trials investigating the potential of *bexmarilimab* in combination with standard of care (SoC) in hematologic cancers will be presented at the European Hematology Association's hybrid EHA2022 Congress in Vienna, Austria, from June 9-12, 2022. These data (Abstract ID: EHA-3535) will be presented on Friday, June 10, 2022 in a session that begins at 16:30 CEST. The abstract can be found here: [EX VIVO IMMUNE ACTIVATION WITH THE MACROPHAGE-TARGETING.... EHA Library. Aakko S. Jun 10 2022; 357243 \(ehaweb.org\)](#)

Faron's wholly-owned novel precision cancer immunotherapy, *bexmarilimab*, targets Clever-1, a receptor known to be expressed on immunosuppressive tumor associated macrophages which make up nearly 50% of the tumor mass and limit the efficacy of currently approved cancer immunotherapies, including anti PD-1/L1. Faron is investigating the potential of this novel immunotherapy in combination with SoC in patients with relapsed acute myeloid leukemia (AML), myelodysplastic syndrome (MDS), or chronic myelomonocytic leukemia (CML), three hematologic cancers for which there are few treatment options.

The data being presented at EHA2022 profiles Clever-1 expression in blood cancer and tests *bexmarilimab's* growth inhibitory and immunomodulatory potential in preclinical models, as a monotherapy and in combination with *azacitidine* and/or *venetoclax*, two standard of care treatments used as in AML, MDS and CML. Results confirmed that Clever-1 is expressed in patient-derived monocytes and blasts. *Ex vivo* treatment with *bexmarilimab*, alone or in combination with *azacitidine* and/or *venetoclax*, demonstrated increased expression of the antigen presenting molecule, human leucocyte antigen DR (HLA-DR). Enhanced antigen presentation allows the immune system to better identify and kill cancer cells

Furthermore, natural killer (NK) cells and CD8+ T cells showed decreased expression of PD-1 and an increase of activation markers – important predictive biomarkers for overcoming resistance to existing immunotherapies. These results help confirm *bexmarilimab's* potential in hematologic malignancies.

"These results reinforce the strong scientific rationale behind our focus on Clever-1 and the potential of *bexmarilimab*, either alone or in combination with standard of care, to treat blood cancers," said Marie-Louise Fjällskog, M.D., Ph.D., Chief Medical Officer of Faron. "High Clever-1 expression is associated with poor survival in certain blood cancer patients and *bexmarilimab* provides a novel treatment approach for these patients, downregulating Clever-1 expression and igniting an effective immune response. We look forward to the imminent start of our hematology cancer clinical trial program to further explore these promising findings."

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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 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.