



Faron Pharmaceuticals Ltd
("Faron or Company")

Faron Pharmaceuticals Doses First Patient in Phase I/II *Bexmarilimab* Combination Study in Hematologic Malignancies

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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 the first patient has been dosed in the Phase I/II BEXMAB study. BEXMAB will investigate *bexmarilimab*, Faron's wholly-owned precision immunotherapy asset, in combination with standard of care (SoC) in multiple hematological malignancies. This marks the first time *bexmarilimab* is being assessed as part of a clinical study in hematologic malignancies.

The primary objective of the BEXMAB study is to determine the safety and tolerability of *bexmarilimab* in combination with SoC (azacitidine) treatment and to identify the recommended Phase II dose. Secondary objectives include characterizing the pharmacokinetic profile of *bexmarilimab* in combination with SoC treatment and to assess the immunogenicity of *bexmarilimab*. Based on initial safety data, there is potential for Phase II expansion and to include a first line triplet therapy of *bexmarilimab*, azacitidine and venetoclax in newly diagnosed acute myeloid leukemia (AML) patients who are not able to tolerate chemotherapy.

"We know that certain blood cancer cells carry significant amounts of cell surface Clever-1, which may limit the body's ability to mount an immune response," said Mika Kontro, M.D., Ph.D., Helsinki University Hospital Comprehensive Cancer Center and Principal Investigator of the BEXMAB trial. "We think that *bexmarilimab* and azacitidine have the potential to work synergistically by controlling disease progression and activating an immune response. This could provide a deeper and more durable clinical benefit compared to what we have seen with monotherapy."

"We are excited to kick-off this important trial, a significant achievement in our development strategy targeting myeloid cell function to overcome immune suppression in the tumor microenvironment," said Marie-Louise Fjällskog, M.D., Ph.D., Chief Medical Officer of Faron. "Extending our clinical research into the combination setting is a logical next step as it allows us to build on *bexmarilimab*'s monotherapy efficacy and safety profile and will help us uncover its full therapeutic potential in tumor types where high Clever-1 expression is known to adversely impact patient outcomes."

For more information please contact:

Investor Contact

Faron Pharmaceuticals

Julia Balanova

VP, Investor Relations

julia.balanova@faron.com

investor.relations@faron.com

Phone: +1 (917) 306-6096

Media Contact

Faron Pharmaceuticals

Eric Van Zanten

VP, Communications

eric.vanzanten@faron.com

Phone: +1 (610) 529-6219

Cairn Financial Advisers LLP, Nomad

Sandy Jamieson, Jo Turner

Phone: +44 (0) 207 213 0880

Peel Hunt LLP, Broker

Christopher Golden, James Steel

Phone: +44 (0) 20 7418 8900

Sisu Partners Oy, Certified Adviser on Nasdaq First North

Juha Karttunen

Phone: +358 (0)40 555 4727

Jukka Järvelä

Phone: +358 (0)50 553 8990

Consilium Strategic Communications

Mary-Jane Elliott, David Daley, Lindsey Neville

faron@consilium-comms.com

Phone: +44 (0)20 3709 5700

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 BEXMAB

The BEXMAB study is a first-in-human open label phase I/II clinical trial investigating *bexmarilimab* in combination with standard of care (SoC) in aggressive hematological malignancies including acute myeloid leukemia (AML) and myelodysplastic syndrome (MDS). The primary objective is to determine the safety and tolerability of *bexmarilimab* in combination with SoC (azacitidine) treatment and to identify the recommended Phase 2 dose. Based on initial safety data, there is potential for expansion to include a first line triplet therapy of *bexmarilimab*, azacitidine and venetoclax in newly diagnosed AML patients who are not able to tolerate chemotherapy. Clever-1 is highly expressed in both AML and MDS and associated with therapy resistance, limited T cell activation and poor outcomes. Directly targeting Clever-1 could limit the replication capacity of cancer cells, increase antigen presentation, ignite an immune response, and allow current chemotherapy treatments to be more effective.

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.

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.