Faron Pharmaceuticals Oy

("Faron or Company")

Inside Information: Encouraging Additional Data for *Bexmarilimab* for the Treatment of Hematological Malignancies

– BEXMAB Study Update

- Objective response observed in 3 out of 5 patients in the first doublet cohort
- 2 of the 3 responders were refractory to prior azacitidine monotherapy
- No additional adverse events observed adding *bexmarilimab* to standard of care
- Rapid enrollment into both doublet and triplet combinations
- CMO Marie-Louise Fjällskog to discuss further details at The Leukemia & Lymphoma Society (LLS) Therapeutic Acceleration Program (TAP) virtual panel on January 18, 2023

Company announcement, January 16, 2023 at 02:00 AM (EST) / 07:00 AM (GMT) / 09:00 AM (EEST)

Inside information

TURKU, FINLAND / BOSTON, MA – Faron Pharmaceuticals Oy (AIM: FARN, First North: FARON), a clinical stage biopharmaceutical company focused on tackling difficult-to-treat cancers and inflammation via precision immunotherapy, today announces objective responses in 3 out of 5 patients dosed in the first doublet cohort of the Company's Phase I/II BEXMAB study. BEXMAB is investigating *bexmarilimab*, Faron's wholly-owned precision immunotherapy asset, in combination with standard of care (SoC) in multiple hematological malignancies.

The responses from these patients are further defined as:

- Complete remission (CR) with incomplete blood count recovery (CRi) in a patient with relapsed/refractory acute myeloid leukemia (AML) observed after 4 treatment cycles
- CR in a patient with previously untreated myelodysplastic syndrome (MDS) observed after 6 cycles of treatment
- Partial remission (PR) in a patient with MDS with prior failure to azacitidine observed after 2 treatment cycles

"The additional BEXMAB data indicates that *bexmarilimab* contributed to positive responses in the refractory setting where patients failed standard of care," said Marie-Louise Fjällskog, M.D., Ph.D., Chief Medical Officer of Faron. "We are excited about the initial promising results and look forward to gathering additional clinical data for more robust read-outs."

The primary objective of the BEXMAB study (https://www.clinicaltrials.gov/ listing: NCT05428969) is to determine the safety and tolerability of *bexmarilimab* in combination with SoC (azacitidine and venetoclax) treatment and to identify the recommended Phase II dose. Secondary objectives include characterizing preliminary efficacy as well as *bexmarilimab's* pharmacokinetic profile in combination with SoC treatment and assessing its immunogenicity.

The first cohort dosed at 1mg/kg of *bexmarilimab* has been completed for the doublet, and currently enrollment is ongoing into the 3mg/kg cohort. The Company has opened the first triplet cohort with *bexmarilimab* (1mg/kg), azacitidine and venetoclax in newly diagnosed AML patients who are not able to tolerate chemotherapy.

In December 2022, the Company announced for the first cohort that the azacitidine-refractory AML patient achieved a CR, with incomplete blood cell count recovery after four treatment cycles. This was followed by full blood count recovery after five treatment cycles. It was also announced that another patient demonstrated a PR, and this patient now has become a CR.

The safety profile remains strong. In December, the Company announced that *bexmarilimab* continues to be well-tolerated with no dose-limiting toxicities or safety concerns observed in the five patients receiving 1mg/kg

weekly dosing together with azacitidine. The 5-patient doublet arm at 3mg/kg is fully enrolled, with the triplet arm at three patients recruited. All sites are in Finland, but the Company anticipates sites in the U.S. to be opened during Q1 2023 to speed up recruitment even further.

Marie-Louise Fjällskog will discuss the most recent BEXMAB findings at the LLS TAP virtual panel on January 18. The panel, titled "European Partners: Dream Big, Make Bold Progress", will highlight companies that have worked in close collaboration with the LLS TAP program, including Faron, to advance their therapeutic portfolios. Register at this link: https://na.eventscloud.com/website/49472/welcome/.

"We are incredibly proud of our work with the LLS TAP," said CEO Markku Jalkanen. "The leadership in hematological malignancies has provided us with not only financial assistance but also invaluable advice and connections to progress the *bexmarilimab* program, especially in the U.S."

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) tumor-associated macrophages (TAMs) in the tumor microenvironment, converting these highly immunosuppressive M2 macrophages to immune stimulating M1 macrophages. 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 myelodysplatic 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 II dose. 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. CLEVER-1 is highly expressed in both AML and MDS and associated with therapy resistance, limited T cell activation and poor outcomes.

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.