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

Bexmarilimab **(Clevegen) development update**

- Cholangiocarcinoma becomes fifth tumour cohort to show early signs of efficacy
- Increased *bexmarilimab* dosing schedule and high baseline regulatory T cell count associated with clinical benefit
- High levels of soluble Clever-1 observed in MATINS patients
- Soluble Clever-1 has the capacity to suppress T cell activation
- Increased *bexmarilimab* dosing frequency to counter high levels of soluble Clever-1 underway

Company announcement, 20 January 2021 at 9.00 AM PM (EEST)
Insider information

TURKU, FINLAND – Faron Pharmaceuticals Oy (AIM: FARN, First North: FARON), a clinical stage biopharmaceutical company, today announces new observations from its ongoing MATINS trial and an update on the study.

The phase I/II MATINS clinical trial is investigating the tolerability, safety and preliminary efficacy of *bexmarilimab*, Faron's wholly-owned novel precision cancer immunotherapy targeting Clever-1, a receptor known to be expressed on immunosuppressive macrophages in the tumour microenvironment.

Working with Kaiku Health Ltd ("Kaiku"), a health data science company (www.kaikuhealth.com), Faron is using Kaiku's artificial intelligence platform designed to analyse patient outcomes following treatment with cancer immunotherapies to undertake further efficacy analysis of patient data from Part I of the MATINS trial. This platform provides insight through data analyses of the immunological and disease characteristics of the MATINS patients to better define patients who respond to *bexmarilimab* and should enable further refinement of *bexmarilimab's* clinical development.

Latest scientific observations from the trial include the identification of a new role for soluble Clever-1, related to its capacity to control T-cell activation. This suggests that the inactivation of Clever-1 as an immune suppressive molecule could be even broader and more important than previously thought as the immune-stimulating effects are not only limited to tumour associated macrophages (TAM) but may also act systemically.

Dr. Markku Jalkanen, Faron's CEO, said: "I am extremely happy about these results and wish to thank our team, our scientific network and the MATINS clinical group for the impressive work they have done, both progressing the trial and undertaking complex analyses of the data during challenging times in the face of the current pandemic. Never during my career have I seen that a high baseline count of regulatory T cells

(Tregs) predicts a good response to a therapy. Until now, it has always been the opposite. This is remarkable. Such observations now provide us with a much better understanding of the next steps required for *bexmarilimab's* clinical development in pivotal studies and support its potential as a breakthrough therapy to deliver optimal clinical results in patients with hard to treat cancers.

"The new discovery of the role of soluble Clever-1 as an immune suppressive molecule is striking, indicating the soluble part of this receptor could cause systemic inhibition of T-cells in all locations of body, therefore controlling the general immune capacity in cancer patients. We hope to be able to overcome this inhibition just by increasing the dosing frequency of *bexmarilimab* to provide maximal binding and the removal of Clever-1 from body fluids and tissues, including tumours."

Data details

Five solid tumour types showing early signs of efficacy

As previously communicated, four solid tumour cohorts in the first expansion stage (Part II) of the study (cutaneous melanoma, colorectal cancer (CRC), hepatocellular cancer and ovarian cancer) have demonstrated early signs of clinical efficacy from *bexmarilimab* therapy. This group is now joined by cholangiocarcinoma (also known as bile duct cancer) as a fifth responsive tumour cohort. The exact way how these cohorts will be taken forward into the protocol for Part III of the MATINS trial will be decided in Q3-2021 after further data on the effect of increased dosing frequency is available (recruitment currently ongoing). More frequent dosing either weekly or at two week intervals could increase *bexmarilimab* treatment efficacy further, compared to the original dosing interval of every three weeks, which has already led to some very promising results in several advanced cancer types.

Regulatory T cell (Treg) marker FOXP3 and increased *bexmarilimab* dosing associated with increased clinical benefit

Part I MATINS study patients had received a median of three previous cancer treatments (mainly various chemotherapy combinations). Half of the study patients had received four or more lines of therapy before joining the MATINS study. Patient blood samples have indicated reduced immune capacity reflected in low counts of effector immune cells. To better understand patient outcomes after *bexmarilimab* treatment around 50 biomarkers have now been analysed using Kaiku's Immuno-Oncology platform resulting in the following findings:

- Increased *bexmarilimab* dosing level with three week interval was associated with a clinical response
- High baseline count of Treg cell marker FOXP3 was associated with a clinical response

These findings are consistent with the Company's previous findings and understanding that cellular immune activation and the removal of immunosuppressive elements are required for clinical benefit from *bexmarilimab*. The association of clinical benefit in patients with a high baseline count of Tregs indicates that patients were significantly immunosuppressed before the treatment. In these subjects, removal of

immunosuppression using *bexmarilimab* to inactivate Clever-1 positive myeloid cells could therefore result in removal of Tregs known to be supported by macrophages. The Company believes that increased dosing frequency has the potential to produce more complete inactivation of Clever-1, either expressed on the surface of myeloid cells or circulating in blood and lymph as a soluble immunosuppressive molecule.

Cancer patient plasma can contain significant amounts of soluble Clever-1

The transient Clever-1 receptor occupancy observed in all MATINS Part I dose levels (0.1-10 mg/kg) supports the decision to increase dosing frequency from every three weeks to either weekly or two week intervals. Latest data show that MATINS patients' plasma (blood devoid of cells) could contain up to a 10-fold increased level of soluble Clever-1 compared to healthy controls. These elevated values could explain the rapid uptake of *bexmarilimab* in cancer patients. This finding also supports the potential of higher administration frequency, which is currently ongoing in CRC patients, with first results expected in H1-2021.

Soluble Clever-1 has the capacity to suppress T cell activation

The role of increased soluble Clever-1 in the circulation was tested in experimental settings. The most interesting finding from this experimental work elucidated a new role for Clever-1: it can control T cell activation directly, including naïve T cells. This is a significant finding because it proposes that by producing soluble Clever-1 the malignant process can also suppress T cell activation in remote locations and, by targeting naïve T cells, can prevent expansion of the T cell repertoire. Soluble Clever-1 can therefore be a substantial inhibitor of T cell activating therapies.

A new patent application has been filed seeking global protection for these findings and related applications.

The observations detailed in this statement are being prepared for peer-reviewed publication and/or presentation at future scientific congresses.

This announcement contains inside information for the purposes of Article 7 of Regulation (EU) No 596/2014 ("MAR").

About *bexmarilimab*

Bexmarilimab is Faron's investigative precision immunotherapy, a novel anti-Clever-1 antibody with the ability to switch immune suppression to immune activation in various conditions, with potential across oncology, infectious disease and vaccine development. Currently in phase I/II clinical development as a novel macrophage checkpoint immunotherapy for patients with untreatable solid tumours, Clevegen has potential as a single-agent therapy or in combination with other standard treatments including immune checkpoint molecules.

About the MATINS study

The MATINS study is the first-in-human open label Phase I/II clinical trial with an adaptive design to investigate the safety and efficacy of *bexmarilimab* in ten selected metastatic or inoperable solid tumours – cholangiocarcinoma, colorectal cancer, cutaneous melanoma, ER+ breast cancer, gastric cancer, hepatocellular carcinoma, ovarian cancer, uveal melanoma, pancreatic cancer and anaplastic thyroid carcinoma – all known to host a significant number of Clever-1 positive tumour associated macrophages (TAM).

Part I of the trial dealt with tolerability, safety and dose escalation to optimize dosing. As the trial is an open label study, the Company expects to report findings as the dosing progresses. The cohort expansion during Part II is focused on identifying patients who show an increased number of Clever-1 positive tumour macrophages and the safety and efficacy of the treatment. During Part III, the main focus will be on assessing the efficacy of Clevegen on study subjects who show an increased number of Clever-1 positive circulating monocytes, making the treatment precisely targeted and maximizing the chances of success for efficacy.

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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. The Company currently has a pipeline based on the receptors involved in regulation of the immune response in oncology and organ damage. Clevegen (*bexmarilimab)*, its investigative precision immunotherapy, is a novel anti-Clever-1 antibody with the ability to switch immune suppression to immune activation in various conditions, with potential across oncology, infectious disease and vaccine development. Currently in phase I/II clinical development as a novel macrophage checkpoint immunotherapy for patients with untreatable solid tumours, Clevegen has potential as a single-agent therapy or in combination with other standard treatments including immune checkpoint molecules. Traumakine, the Company's pipeline candidate to prevent vascular leakage and organ failures is currently being tested in several Phase III studies around the world against COVID-19. Traumakine is intravenous IFN beta-1a, which is a strong anti-viral and anti-inflammatory agent. Faron is based in Turku, Finland. Further information is available at www.faron.com

Caution regarding 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.