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

Bexmarilimab **(Clevegen) development update**

- *Accumulating MATINS data build foundation for further clinical development*
- *Five patient cohorts in MATINS study Part II already fully recruited*
- *Higher frequency of dosing introduced to investigate potential for enhanced clinical responses*
- *Three new trials will study bexmarilimab treatment in neoadjuvant setting, in combination with PD(L)-1 checkpoint inhibitor and in haematological malignancies*

Company announcement, 23 November 2020 at 9.00 AM (EET)

TURKU – FINLAND – Faron Pharmaceuticals Oy (AIM: FARN, First North: FARON), the clinical stage biopharmaceutical company, announces today an update on the MATINS study and further details on the clinical expansion plans for *bexmarilimab*, its wholly-owned novel precision cancer immunotherapy, targeting Clever-1 positive tumour associated macrophages (TAMs) in selected metastatic or inoperable solid tumours.

The expanded clinical development programme is intended to generate data beyond existing hard-to-treat cancer cohorts, exploring new patient populations and investigating combinations with existing treatments, to build full understanding of *bexmarilimab's* commercial potential dependent on this unique and proprietary myeloid cell target.

MATINS study update

The ongoing phase I/II MATINS clinical trial is investigating the tolerability, safety and efficacy of *bexmarilimab* across ten different hard-to-treat solid tumour cohorts (cutaneous melanoma, uveal melanoma, ovarian cancer, colorectal cancer, hepatocellular cancer, ER+ breast cancer, pancreatic cancer, gastric cancer, cholangiocarcinoma, anaplastic thyroid carcinoma) in the first expansion stage (Part II) of the study. Latest data from four cohorts – cutaneous melanoma, ovarian cancer, colorectal cancer (CRC), and hepatocellular cancer – have demonstrated early signs of efficacy from *bexmarilimab* monotherapy which, according to the MATINS study protocol, allows them to move to Part III. Further data from all cohorts in Part II will enable the Company to evaluate which indications are most likely to achieve success and should be continued further in development.

Of the cohorts in Part II, uveal melanoma, ovarian cancer, colorectal cancer, pancreatic cancer, and cholangiocarcinoma are now fully recruited and the rest, between 50-90 per cent recruited, except anaplastic thyroid carcinoma, which is a new cohort awaiting enrolment of the first patient.

Investigating alternative dosing schedules

As a result of key pharmacokinetic and pharmacodynamic biomarkers suggesting the potential for improved clinical response of *bexmarilimab* administered with a higher frequency than the current three week interval, regulatory authorities have approved an expansion of MATINS to include two additional CRC cohorts receiving 1 mg/kg dosed at either weekly or two week intervals. These cohorts have started recruiting with results expected during H1 2021. Data from these cohorts will support the design of new and pivotal trials for *bexmarilimab*.

Study of neoadjuvant *bexmarilimab* in colorectal and kidney cancers

Faron expects to initiate a neoadjuvant *bexmarilimab* study in colorectal cancer and clear cell renal cell carcinoma (ccRCC) patients soon after diagnosis and prior to any other treatments. The Company plans to evaluate *bexmarilimab's* ability to induce an anti-cancer immune response in patients previously untreated or with minimal exposure to anti-cancer treatments. Disease-free survival will be also investigated to determine the clinical benefit for neoadjuvant treatment.

Lung cancer combination study with anti-PD-(L)1 therapy

The Company previously reported that *bexmarilimab* administration down regulates a range of immune checkpoint molecules (CTL-4, PDL-1 and PD-1) on the peripheral immune cells of cancer patients, signalling immune activation and removal of T cell exhaustion. This finding is consistent with the current understanding that Clever-1 is major source of T cell exhaustion and treatment resistance against marketed checkpoint inhibitors[1]. Based on these findings, Faron now plans to expand the *bexmarilimab* programme to evaluate its safety and efficacy in a pilot study in combination with anti-PD-(L)1 therapy in non-small cell lung carcinoma (NSCLC) patients, where PD-(L)1 inhibition has become the standard of care, though resistance develops in roughly 70 per cent of patients[2].

Potential of *bexmarilimab* in haematological cancers

Faron, together with Helsinki University Hospital, Finland, plans to initiate a phase I/II *bexmarilimab* study in combination with standard of care in acute myeloid leukaemia (AML)/ myelodysplastic syndrome (MDS) patients in H2 2021 to investigate the safety and preliminary efficacy of *bexmarilimab* in haematological cancers. Both AML and MDS originate from myeloid lineage of bone marrow cells and result in impaired haematopoiesis (the production of blood and immune cells). Due to this nature of cell origin, they also express cell surface Clever-1, which has been identified as a prognostic factor in AML[3]. Faron believes that controlling Clever-1 activity on malignant cells can also control their replication. This is evident in *ex vivo* experimental settings and could be potentiated with anti-apoptotic compounds like bcl-2 inhibitors[3] which promote cell death. Diagnostics and *ex vivo* drug screen development for *bexmarilimab* will be included in the study to optimise patient outcomes for targeted *bexmarilimab* therapy.

Dr. Markku Jalkanen, Faron's CEO, said: "*Bexmarilimab* is rapidly advancing through development and its exciting clinical activity across multiple cancer types continues to give us confidence in this asset's potential as a next generation immunotherapy with broad opportunities. With the data we have seen to-date, we are pleased to expand our *bexmarilimab* development programme, giving us the opportunity to explore its

potential to activate the immune system in early stage cancers and in combination with checkpoint inhibitors, a study of high interest for everyone in the field."

"Our deep understanding of Clever-1 and its role in cancer immunotherapy has brought us to where we are today and we look forward to advancing this novel programme into haematological cancers, the neoadjuvant setting and combination trials, in addition to our ongoing robust basket study in late-line solid tumours, which produces continuous data and understanding of *bexmarilimab* as a foundational treatment for the removal of immune suppression and T cell exhaustion."

References:

1) Hollmén et al. *Brit. J. Cancer* 2020
2) Gandhi et al. *N. Eng. J. Med.* 2018; 378; 2078-92
3) Lin et al. *Mol. Therapy Nucleic Acids* 2019; 18; 476-484

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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. The Company currently has a pipeline based on the receptors involved in regulation of 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.