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

Faron receives regulatory approval from FDA to expand MATINS trial for Clevegen into the USA

Company announcement, Turku, Finland, 28 November 2019 at 09 AM (EET)
Inside information

TURKU - FINLAND, 28 November 2019 - Faron Pharmaceuticals Ltd ("Faron") (AIM: FARN), the clinical stage biopharmaceutical company, today announces that the US Food and Drug Administration (FDA) has approved the Company's Investigational New Drug (IND) application for Clevegen® (FP-1305), enabling expansion of its ongoing MATINS trial into the US.

The phase I/II MATINS clinical trial, already underway in sites through Europe, is investigating the tolerability, safety and efficacy of Clevegen, Faron's wholly-owned novel precision cancer immunotherapy targeting Clever-1 positive tumour associated macrophages (TAM), in selected metastatic or inoperable solid tumours. Following this US IND acceptance, and as soon as the ongoing dose optimization has been completed, Faron plans to open new study sites in the US to facilitate a rapid expansion of part II of the study, investigating the safety and efficacy of Clevegen in various cancer cohorts. Part I of the trial, to optimize dosing, is ongoing but has already provided data on the different candidate cohorts (e.g. hepatocellular cancer) indicating which should be investigated in part II, alongside colorectal cancer.

Dr Markku Jalkanen, CEO of Faron, said: *"We are very pleased to receive this IND approval from the FDA, marking another milestone in the developmet of Clevegen. This approval will allow us to expand MATINS into the US using the same protocol both in Europe and in the US, accelerating our understanding of this novel precision medicine in cancer patients who are refractory to all other treatment options and streamlining the regulatory processes. With the US IND now approved, in due course, we plan to file applications for Breakthrough status in the US and Prime status in Europe, further facilitating regulatory interactions during the development of Clevegen."*

Through the MATINS study, Clevegen has demonstrated good tolerability at all dosing levels (0.3-10 mg/kg) without dose limiting toxicity. The previously reported immune activation of MATINS patients (increased circulating CD8+ T cells and CD8+/CD4+ ratio, decreased regulatory T-cells (T-regs) or a substantial increase in mobile natural killer (NK) cells in the blood) will be used to optimize final dosing, as these changes are needed to activate complete adaptive immune response including an activation of B-cells to maintain cancer immunity against that particular cancer type.

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 Clevegen in selected metastatic or inoperable solid tumours. The selected tumours tumour types currently under investigation are cutaneous melanoma, hepatobiliary/hepatocellular, pancreatic, ovarian and colorectal cancer, all known to host a significant number of Clever-1 positive tumour associated macrophages (TAMs). All together these five target groups consist of approximately 2 million annual cases worldwide. Cancer patients with high Clever-1 expression are identified with a simple blood myeloid cell staining with Clevegen ("liquid biopsy").

Part I of the trial investigates 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 will focus on the safety and efficacy of the FP-1305 in distinct cancer types, including the already announced colorectal cancer (CRC). During Part III, the main focus will be on assessing the efficacy of Clevegen on study subjects who with increased number of Clever-1 positive circulating monocytes, making the treatment precisely targeted and maximizing the chances of success for efficacy. The treatment, if successful, may ultimately be used as a standalone therapy or in combination with other immunotherapies like PD-1 inhibitors.

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

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About Faron Pharmaceuticals Ltd

Faron (AIM:FARN) 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 endothelial receptors involved in regulation of immune response, in oncology and organ damage. Clevegen®, its 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 immune checkpoint molecules or other cancer standard cares. Traumakine®, the Company's pipeline candidate to prevent vascular leakage and organ failures, has completed a phase III clinical trial in Acute Respiratory Distress Syndrome (ARDS). Plans for its future development are being finalised to avoid interfering steroid use together with Traumakine®. 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.