

Part 1 of the MATINS Phase I/II Study Completed

Faron Pharmaceuticals Oy

("Faron" or the "Company")

Completion of Part 1 dose finding stage of the MATINS Phase I/II Study

Study data monitoring committee recommends rapid expansion of study into new tumour types following promising results

Company announcement, 30 March 2020 at 9.00 AM (EET)

Inside information

TURKU - FINLAND - Faron Pharmaceuticals Oy (AIM: FARN, First North: FARON), the clinical stage biopharmaceutical company, today announces positive feedback from the MATINS study data monitoring committee ("DMC") following a comprehensive review and analysis of the data from the now completed Part 1 (dose finding) stage of the trial.

The ongoing phase I/II MATINS clinical trial 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. The DMC has reviewed all available data, including imaging and biomarker analyses from the 30 patients treated in Part 1 of the trial. The reviewed biomarker (cellular and biochemical) data is from the first cycle of all 30 patients and target tumour lesion images according to RECIST between the third and fourth cycles (roughly 60-70 days from the first dose).

The following key findings were presented to the DMC:

Immune switch. Consistent with earlier analyses, immune activation was observed in all subjects (except patients receiving 0.1 mg/kg) measured following treatment with Clevegen and was observed as 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. This activation was dose dependent. Interestingly, 12 patients showed at least a 20 per cent increase in interferon gamma and eight patients a similar increase in IP-10 chemokine production. Interferon gamma is known to restrict cancer growth and IP-10 to attract T-lymphocytes to infiltrate the tumour.

Clinical response. According to the RECIST classification, Clevegen treatment showed a clinical effect of two partial responses (as previously announced), and seven cases of stable disease. None of the patients experiencing these effects had received the lowest dose level of 0.1mg/kg, therefore the response rate in Part I was 36 percent (9/25) among 0.3-10 mg/kg dose levels.

DMC recommendation. The MATINS DMC has now reviewed all available data on Part I patients and the Company has received advice to continue the trial as planned with the following notes:

- Dose escalation reached its planned maximum level of 10mg/kg with Clevegen demonstrating good tolerability at all dosing levels (0.1 to 10 mg/kg) without dose limiting toxicity. A maximally tolerated dose (MTD) was not reached. The DMC recommends that all further administration of Clevegen should take place at 1mg/kg.
- Part 2 of the study should now be expanded to include all cancer cohorts in the study protocol, beyond the colorectal and ovarian cancer cohorts previously selected and announced (see list below).
- Patient recruitment for the expansion cohorts should follow standard of care for each cancer type and enable subjects with less compromised immune systems (i.e., earlier treatment lines whenever possible according to the study protocol) to be enrolled to the trial.

Dr. Markku Jalkanen, Faron's CEO, said: "We welcome the support from the data monitoring committee to expand our studies, exploring the safety and efficacy of Clevegen in additional cancer types. We continue to be highly encouraged by the consistency of the data from the MATINS trial indicating Clevegen's strong immune switch and the low dosing levels required to show these responses, but most importantly its clinical effect on tumour lesions in patients who have exhausted all treatment options.

"We will now work with trial sites in the MATINS network across Europe and the US to ensure expansion of the trial beyond the colorectal and ovarian cancer cohorts already recruiting. We look forward to generating further data to assess the durability of effect and efficacy of Clevegen in larger numbers of patients."

Subject to funding, additional cancer types besides colorectal and ovarian to be included in Part 2 of the MATINS study are:

- ER-positive breast cancer
- Hepatocellular carcinoma
- Cholangiocarcinoma (bile duct cancer) and gall bladder cancer
- Gastric cancer
- Hepatocellular carcinoma
- Cutaneous melanoma
- Uveal melanoma
- Pancreatic ductal adenocarcinoma

Ten patients are expected to be treated in each of the cohorts. The first colorectal cancer cohort has already been recruited and dosed at the previously agreed 0.3 mg/kg dosing level. As noted above, going forwards all future dosing will be at 1 mg/kg. The Company has received feedback from the study sites that the initiation of new cohorts may be delayed due to restricted resources caused by corona infections. The Company will work closely with these trial sites to ensure the trial progresses as smoothly as possible.

RECIST: Response evaluation criteria in solid tumours is a set of published rules that define when tumors in cancer patients improve ("respond"), stay the same ("stabilize"), or worsen ("progress") during treatment.

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

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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 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 (TAM). 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 deals 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 will focus on identification of patients who show an increased number of Clever-1 positive circulating monocytes and the safety and efficacy of the treatment. Colorectal cancer and ovarian cancer have been selected as the first and second expansion cohorts in Part II. 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. The treatment, if successful, may ultimately be used as a standalone therapy or in combination with other immunotherapies like PD-1 inhibitors.

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, 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 standard treatments including immune checkpoint molecules. 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.

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