FDA accepts protocol for new Traumakine trial

Faron Pharmaceuticals Oy

("Faron" or the "Company")

FDA accepts protocol for new Traumakine trial in ARDS

Company announcement, 09 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 that the U.S. Food and Drug Administration (FDA) has accepted the proposed protocol design for the next Traumakine study in ARDS patients, following the Company's protocol submission announced on 6 February 2020.

The trial protocol reflects the feedback and conclusions from the FDA that further studies with interferon-beta (IFN beta-1a) should exclude the use of concomitant glucocorticoids since they are likely to block the desired therapeutic effect of Traumakine and may have a potentially deleterious impact on patient survival. This harmful interaction has been previously evidenced both clinically in the INTEREST study, where concomitant glucocorticoids use was associated with increased mortality, and experimentally *ex vivo* using human lung tissue and pulmonary endothelial cells.

Faron is planning to split the clinical development of Traumakine in ARDS into two steps, commencing with INTEGRITY, a pilot randomised and placebo controlled study with approximately 60 patients. The INTEGRITY data will then serve as final adjustment for adequate statistical powering and sample size justification for the pivotal CALIBER study, subjected for FDA review. The Company expects that the sample size of the CALIBER study will not exceed 200 patients based on the post hoc analysis of the INTEREST trial data. As previously announced, the Company envisages that future Traumakine trials (including INTEGRITY and CALIBER) are likely to be funded through a third party or parties.

Dr. Markku Jalkanen, Faron's CEO, said: "FDA's acceptance of our proposed study design and protocol is a significant step for the future development of Traumakine. Our learnings from previous trials in this development programme have enabled us to refocus our efforts on Traumakine, which we continue to believe holds great potential as a future treatment for ARDS, including flu or corona virus infected people. We look forward to providing further updates as our funding discussions with third parties progress."

Ends

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, 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.