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

Faron Pharmaceuticals Doses First Patient in Phase II/III HIBISCUS Trial of Traumakine for Treatment of Hospitalized COVID-19 Patients

- Trial co-funded by US Department of Defense

Company announcement, August 25, 2021 at 9.00 AM (EEST)
Inside information

TURKU, FINLAND / BOSTON, MA – Faron Pharmaceuticals Oy (AIM: FARN, First North: FARON), a clinical stage biopharmaceutical company focused on building the future of immunotherapy by harnessing the power of the immune system to tackle cancer and inflammation, today announced that the first patient has been dosed in the Phase II/III HIBISCUS trial assessing Traumakine (Intravenous Interferon beta-1a; IFN beta-1a) as a first-line treatment for hospitalized COVID-19 patients. Traumakine is an investigational therapy developed by Faron for the potential treatment of acute respiratory distress syndrome (ARDS), acute kidney injury, cardiac protection, prevention of solid organ transplant failure and ischemia reperfusion injury.

The HIBISCUS study will be conducted in approximately 10-15 study sites across the US and will enroll 140 patients who require low flow oxygen support, but not mechanical ventilation. Patients will be randomized 1:1 across two study arms to assess the safety and efficacy of Traumakine compared to corticosteroid treatment with dexamethasone. As part of the trial protocol, corticosteroid treatment concomitantly with Traumakine is not possible in the study setting but is enabled in a sequenced manner following treatment with Traumakine. The primary efficacy endpoint is clinical status (WHO 9-point ordinal scale) at day 14. Key secondary endpoints for the study include clinical status at day 28 and in-hospital mortality at days 28 and 90.

"There are currently limited treatment options for hospitalized COVID-19 patients, many of whom spend months in the hospital and face the potential of lifelong complications associated with their disease," said Daniel S. Talmor, M.D., MPH, Chief of Anesthesia, Critical Care and Pain Medicine at Beth Israel Deaconess Medical Center and Principal Investigator of the HIBISCUS trial. "We are pleased to commence this pivotal Phase II/III trial as we believe intravenous IFN beta-1a has the potential to become a powerful treatment option for patients who are at risk of developing acute respiratory distress syndrome as a consequence of a viral infection, such as COVID-19."

"Despite the progress that has been made with vaccinations, there remains a critical need to identify effective treatment options for hospitalized COVID-19 patients," said Dr. Markku Jalkanen, Chief Executive Officer of Faron. "As we continue to gain insight into the potential benefit of IFN beta-1a as the body's first line of defense against viral infection, we believe Traumakine will be advantageous over current standard of care to protect lung function post COVID-19 infection. We are proud to be engaged in research to support the ongoing global response to COVID-19 and are pleased to be working with the US Department of Defense and the team at Harvard University's Beth Israel Deaconess Medical Center on this study."

In January 2021, Faron announced that the US Department of Defense (DoD) had selected the HIBISCUS trial to receive $6.1 million of funding from the Coronavirus Aid, Relief, and Economic Security (CARES) Act. Additionally, as part of an ongoing working relationship established with Faron, the 59th Medical Wing of the US Air Force and the DoD are continuing preclinical studies to evaluate Traumakine's role in preventing multiple organ dysfunction syndrome (MODS) after ischemia-reperfusion injury caused by a major trauma.

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 caused by dysfunction of our immune system. The Company currently has a pipeline based on the receptors involved in regulation of immune response in oncology, organ damage and bone marrow regeneration. *Bexmarilimab,* a novel anti-Clever-1

humanised antibody, is its investigative precision immunotherapy with the potential to provide permanent immune stimulation for difficult-to-treat cancers through targeting myeloid function. Currently in Phase I/II clinical development as a potential therapy for patients with untreatable solid tumors, bexmarilimab has potential as a single-agent therapy or in combination with other standard treatments including immune checkpoint molecules. Traumakine is an investigational intravenous (IV) interferon beta-1a therapy for the treatment of acute respiratory distress syndrome (ARDS) and other ischemic or hyperinflammatory conditions. Traumakine is currently being evaluated in global trials as a potential treatment for hospitalized patients with COVID-19 and with the 59th Medical Wing of the US Air Force and the US Department of Defense for the prevention of multiple organ dysfunction syndrome (MODS) after ischemia-reperfusion injury caused by a major trauma. Faron is based in Turku, Finland. Further information is available at www.faron.com.

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, early data may not be replicated in larger patient numbers and the outcome of clinical trials may not be favorable 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.