



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

Faron Closes HIBISCUS Trial Due to Low COVID-19 Infection and Hospitalization Rates in the US and Reverts Resources to the Development of *Bexmarilimab*

- *Traumakine will be re-positioned for multiple indications in organ protection together with partnerships*
- *Near term value inflections are expected from the accelerated development of *Bexmarilimab**

Company announcement, April 05, 2022 at 09:00 AM (EET) / 07:00 AM (GMT) / 2:00 AM (EDT)

Inside information

TURKU, FINLAND / BOSTON, MA – Faron Pharmaceuticals Ltd (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, due to low COVID-19 hospitalization rates and a shortage of patients not already receiving steroids, the Company is closing its Phase II/III HIBISCUS trial assessing Traumakine (Intravenous Interferon beta-1a; IFN beta-1a) as a first-line treatment for hospitalized COVID-19 patients who require low flow oxygen support. The Company's decision was based on a recommendation from the HIBISCUS Independent Data Monitoring Committee (IDMC) to discontinue the study due to slow recruitment. The IDMC also informed the Company that there were no safety concerns related to treatment of enrolled patients.

"When the HIBISCUS trial was designed and initiated, infection and hospitalization rates were high across the U.S.," said Dr. Markku Jalkanen, Chief Executive Officer of Faron. "The emergence of the less severe Omicron variant and widespread vaccinations led to a significant decrease in the number of hospitalized patients requiring low flow oxygen support. While this was good news from a pandemic perspective, it, along with the widespread early use of steroids, severely limited our potential patient pool. As a result and based on a recommendation from the independent data monitoring committee, we made the decision to end patient enrollment in the HIBISCUS trial and re-focus immediate resources on the development of *bexmarilimab*."

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. The DoD concurs with the IDMC and Faron that given the current environment the trial will not be able to enroll in a timely manner and enrollment should be stopped. Faron will continue to partner with the 59th Medical Wing of the US Air Force and the DoD on preclinical studies to evaluate Traumakine's role in preventing multiple organ dysfunction syndrome (MODS) after ischemia-reperfusion injury caused by a major trauma.

"We know that intravenous interferon beta-1a can up-regulate CD73, which reduces inflammation and prevents vascular leakage," 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. "While the timing and scope of the HIBISCUS trial did not allow us to efficiently enroll patients, I believe strongly that Traumakine has the potential to become a powerful treatment option for patients who are at risk of developing major inflammation and look forward to continuing to work with Faron to advance this potentially first-in-class treatment approach in multiple settings."

"We want to thank the patients, their caregivers, the investigators and everyone who participated in the HIBISCUS trial," said Dr. Juho Jalkanen, Chief Operating Officer of Faron. "Data from this partially completed study will support our ongoing Traumakine development strategy, which we expect will include additional studies exploring its potential as a future treatment for multiple acute settings of ischemia and systemic inflammation leading to vascular dysfunction and organ damage. We expect ongoing Traumakine development efforts will be supported by both academic and industry collaborations."

Traumakine is an investigational therapy developed by Faron for the potential treatment of conditions based on major inflammation and vascular dysfunction such as acute respiratory distress syndrome (ARDS), acute kidney injury, cardiac protection and ischemia reperfusion injury. The HIBISCUS trial opened enrollment and began recruiting patients at sites in the U.S. in August 2021. The trial was meant to enroll 140 patients who required low flow oxygen support, but not mechanical ventilation. Enrolled patients were 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 was not

possible in the study setting but was enabled in a sequenced manner following treatment with Traumakine. No treatment related safety concerns were reported among enrolled patients.

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 humanized 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, 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.