

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

### Faron Pharmaceuticals Announces Top-Line 12-Month Survival Results Across 10 Advanced Solid Tumors

- 65% of patients who benefited from treatment with bexmarilimab were alive at 12-months compared to 11% for patients who did not benefit from treatment
- The strongest survival benefit was seen in checkpoint refractory melanoma and cholangiocarcinoma where 12-month survival was 100% among patients who benefited from bexmarilimab treatment and 0% for patients who did not benefit from treatment
- Analysis includes heavily pre-treated, advanced disease patients from 10 solid tumor cohorts
- Treatment with bexmarilimab continues to be well tolerated with no treatment related adverse events resulting in a
  decrease or modification of dosing

Company Announcement, June 15, 2022 at 02:00 AM (EST) / 07:00 AM (BST) / 09:00 AM (EEST) Insider 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 announces 12-month top-line overall survival results from its Phase I/II MATINS (Macrophage Antibody To INhibit immune Suppression) study investigating the safety and efficacy of bexmarilimab monotherapy in ten different hard-to-treat metastatic or inoperable solid tumor cohorts. The analysis showed that 65% (11/17) of patients who benefited from treatment with bexmarilimab (partial response + stable disease rate) were alive at 12-months compared to 11% (8/73) of patients who did not benefit from treatment. The strongest survival benefit was seen in checkpoint refractory melanoma and cholangiocarcinoma where 12-month survival was 100% among patients who benefited from bexmarilimab treatment and 0% for patients who did not benefit from treatment. The analysis includes 90 patients from the trial who received three courses of treatment and had their scheduled tumor imaging at cycle four and 12-month survival follow-up completed.

"The updated survival data from the MATINS trial are significant, especially when you consider the patient population in this trial," said Daruka Mahadevan, M.D. Ph.D., Chief, Division of Hematology/Medical Oncology, Mays Cancer Center, University of Texas Health, San Antonio. "These are heavily pre-treated patients with significantly advanced disease. It's highly encouraging that an anti-tumor immune response was activated and that two-thirds of the patients who benefited from treatment had a durable response lasting at least 12-months."

The ongoing open label Phase I/II MATINS clinical trial is investigating the safety and efficacy of bexmarilimab, Faron's whollyowned novel precision cancer immunotherapy targeting Clever-1, a receptor known to be expressed on immunosuppressive macrophages in the tumor microenvironment. In the MATINS trial, bexmarilimab is being investigated as a potential monotherapy in patients with solid tumors who have exhausted all other treatment options. The most significant clinical benefit rate among the ten solid tumor cohorts was observed in cutaneous melanoma (30%), gastric cancer (30%), cholangiocarcinoma (30%), hepatocellular carcinoma (40%) and breast cancer (40%) patients. Treatment with *bexmarilimab* continues to be well tolerated with no new safety signals reported and no treatment related adverse events resulting in a decrease or modification of dosing.

"One-year survival data is an important milestone in any cancer trial, and we are highly encouraged by the meaningful extension of life experienced by patients who benefited from bexmarilimab monotherapy," said Marie-Louise Fjällskog, M.D., Ph.D., Chief Medical Officer of Faron. "These data, along with the biomarker data we previously reported, are helping us design our upcoming registrational trials and further support our belief that bexmarilimab monotherapy can increase survival in patients with a variety of late-stage solid tumors."

The Company will complete a detailed evaluation of the MATINS data and looks forward to sharing the results at an upcoming medical conference, as well as with regulatory authorities. Faron thanks the patients and investigators who are participating in the MATINS clinical trial. This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 960914.

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

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## About Bexmarilimab

*Bexmarilimab* is Faron's wholly-owned, investigative precision immunotherapy with the potential to provide permanent immune stimulation for difficult-to-treat cancers through targeting myeloid cell function. A novel anti-Clever-1 humanised antibody, *bexmarilimab* targets Clever-1 positive (Common Lymphatic Endothelial and Vascular Endothelial Receptor 1) tumour associated macrophages (TAMs) in the tumour microenvironment, converting these highly immunosuppressive M2 macrophages to immune stimulating M1 macrophages. In mouse models, *bexmarilimab* has successfully blocked or silenced Clever-1, activating antigen presentation and promoting interferon gamma secretion by leukocytes. Additional pre-clinical studies have proven that Clever-1, encoded by the Stabilin-1 or STAB-1 gene, is a major source of T cell exhaustion and involved in cancer growth and spread. Observations from clinical studies to date indicate that Clever-1 has the capacity to control T cell activation directly, suggesting that the inactivation of Clever-1 as an immune suppressive molecule could be more broadly applicable and more important than previously thought. As an immuno-oncology therapy, *bexmarilimab* has potential as a single-agent therapy or in combination with other standard treatments including immune checkpoint molecules in both solid tumors and hematologic malignancies. Beyond immuno-oncology, it offers potential in infectious diseases, vaccine development and more.

## About MATINS

The MATINS (Macrophage Antibody To INhibit immune Suppression) study is a first-in-human open label phase I/II clinical trial investigating the tolerability, safety and efficacy of *bexmarilimab* in ten different hard-to-treat metastatic or inoperable solid tumour cohorts - cholangiocarcinoma, colorectal cancer, cutaneous melanoma, ER+ breast cancer, gastric cancer, hepatocellular carcinoma, ovarian cancer, uveal melanoma, pancreatic cancer and anaplastic thyroid carcinoma - which are all known to host a significant number of Clever-1 positive tumour-associated macrophages (TAMs). The completed Part I of the trial dealt with tolerability, safety and dose escalation. The ongoing Part II is focused on identifying patients who show an increased number of



Clever-1 positive TAMs and exploring safety and efficacy. Part III will be focused on assessing efficacy. Data from MATINS have shown that bexmarilimab has the potential to be the first macrophage immune checkpoint therapy. To date, the investigational therapy has been shown to be safe and well-tolerated, making it a low-risk candidate for combination with existing cancer therapies, and has demonstrated early signs of clinical benefit in patients who have exhausted all other treatment options.

### 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 solid tumors and hematologic malignancies, *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 by 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 <u>www.faron.com</u>.

### **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 forwardlooking 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.