

# **Faron Pharmaceuticals Ltd** ("Faron" or the "Company")

## Faron Provides Update on Bexmarilimab Development Program Ahead of R&D Day

- Updated landmark analysis estimates nine-month overall survival rates were 70% for heavily pre-treated, late-stage cancer patients who benefited from treatment with *bexmarilimab* and 26% for patients who did not benefit from treatment
- Biomarker analysis showed widely available blood tests can identity which patients are likely to receive clinical benefit from treatment with *bexmarilimab*
- Treatment with *bexmarilimab* continues to be well tolerated with no treatment related adverse events resulting in a decrease or modification of dosing
- Company to host virtual R&D Day webcast today, Wednesday, February 23, at 4:00 pm EET, 2:00 pm GMT, 9:00 am EDT

#### Company announcement, February 23, 2022 at 09:00 AM (EET) / 07:00 AM (GMT) / 02:00 AM (EDT)

**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 updated survival data from Phase I/II MATINS (Macrophage Antibody To INhibit immune Suppression) study investigating the safety and efficacy of *bexmarilimab*. The data will be presented at the Company's virtual R&D Day webcast today, Wednesday, February 23, at 4:00 pm EET, 2:00 pm GMT, 9:00 am EDT. To register for Faron's R&D Day webcast, please visit: <u>https://faron.videosync.fi/r-and-d-day</u>.

The updated results from the MATINS study include patients from Part I (30 patients) and Part II (110 patients) of the trial. For all these patients, the estimated median progression free survival (PFS) is 59 days (95% confidence interval, 58-61). The estimated median overall survival (OS) is 157 days (95% confidence interval, 128-192).

Landmark OS for Part I/II patients who received three courses of treatment and had their scheduled tumor imaging at cycle four (n=92) estimated that 70% of disease control rate (DCR = partial response + stable disease rate) patients were alive at nine months after the landmark (that is, approximately 11 months from initiation of treatment) compared to 26% of non-DCR patients. The most significant disease control rate (DCR) among Part II 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.

As previously announced, patients with low interferon gamma (IFNy) and tumor necrosis factor alpha (TNFa) levels experienced significantly higher clinical benefit following treatment with *bexmarilimab*. This is the opposite to what is usually seen with checkpoint inhibitors and other T cell activating agents. Additionally, a more than 100% increase in IFNy levels was seen after the first cycle of *bexmarilimab treatment* among patients who experienced clinical benefit.

As part of an ongoing biomarker analysis, receiver operating characteristic (ROC) curves found that low levels of both IFNy and TNFa was highly predictive of clinical benefit (AUC 0.83, P < 0.0001). Likelihood of clinical benefit increased even higher (AUC 0.9107, P < 0.0001) when low levels of IL-6 & IL-8 were also present. These four inflammatory biomarkers can easily be identified by simple, inexpensive and readily available blood tests. The ability to have these classical pro-inflammatory cytokines measured as part of a patient's routine clinical care could expedite treatment decisions improving patient care, which today requires costly biopsies and pathology tests.



"The updated MATINS data shows even more clearly that heavily pre-treated, late-stage cancer patients who receive clinical benefit from *bexmarilimab* can achieve long term survival," said Marie-Louise Fjällskog, M.D., Ph.D., Chief Medical Officer of Faron. "The ongoing biomarker analysis is also helping us better identify which patients are likely to respond and what happens in the tumor microenvironment when patients are treated with *bexmarilimab*."

The Company will host a virtual R&D Day webcast today, Wednesday, February 23, at 4:00 pm EET, 2:00 pm GMT, 9:00 am EDT. To register to participate in the virtual webcast, please visit: <u>https://faron.videosync.fi/r-and-d-day</u>.

Dr. Markku Jalkanen, Chief Executive Officer of Faron, will host the event together with members of Faron's Global Leadership Team. In addition, the following external experts will provide additional perspectives on the immunotherapy treatment landscape and how *bexmarilimab* may help address the significant unmet medical need that continues to exist:

- Dr. Tyler Curiel, Professor of Medicine and Microbiology, Immunology & Molecular Genetics at The University of Texas Health Science Center at San Antonio, United States
- Dr. Maija Hollmén, Adjunct Professor of Tumour Immunology, Group Leader and Academy Research Fellow at the MediCity Research Laboratory, Institute of Biomedicine, University of Turku, Finland

"I look forward to hosting our virtual R&D Day and providing an update on the current treatment landscape and what we are doing to help address the significant unmet medical needs of cancer patients," said Dr. Markku Jalkanen, Chief Executive Officer of Faron. "Our accelerated *bexmarilimab* development plan, which in addition to the ongoing MATINS trial includes plans to study bexmarilimab in combination with other checkpoint inhibitors and as a treatment for hematological malignancies, is ambitious, but given the data we have seen to date and our evolving understanding of which biomarkers will predict response to treatment, we are confident that we can progress each of these programs forward and potentially have an extremely broad impact on cancer care."

A Finnish language interview with Dr. Markku Jalkanen covering the important information shared during the R&D Day event will also take place on February 23, 2022. A link to a recording of this interview will be made available on the "Investors" section on Faron's website at: <u>https://www.faron.com/investors</u>.

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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. 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 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

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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 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.