

**Faron Pharmaceuticals Ltd.**

("Faron" or "the Company")

**Faron's Capital Markets Day 2024 - BEXMAB follow-up data and update on drug development pipeline,  
partnering discussions and introducing new Scientific Advisory Board**

*Company Announcement, 22 October 2024*

**TURKU, FINLAND-** Faron Pharmaceuticals Ltd. (AIM: FARN, First North: FARONa clinical-stage biopharmaceutical company focused on tackling cancers via novel immunotherapies, will host a Capital Markets Day for investors, analysts and media today, Tuesday, 22 October 2024 at 08:00 am (EDT) / 13:00 pm (BST) / 15:00 pm (EEST). Speakers are Dr. Mika Kontro, MD, PhD, Associate Professor at the University of Helsinki, Mr. Ralph Hughes, MSc, BSc, Senior Vice President at PharmaVentures and Faron's senior management members.

**BEXMAB Follow Up Data Continue to Indicate High Overall Response Rate**

The BEXMAB Phase I/II trial results have already indicated a high overall response rate (ORR) of 79% (11 out of 14) amongst relapsed and refractory myelodysplastic syndrome (r/r MDS) patients treated with a combination of *bexmarilimab* + azacitidine. Similar size patient cohorts treated with existing alternatives have reported 0-20% ORR, without deep and durable remissions.

Previously estimated median overall survival (mOS) was approximately 13.4 months with 14 r/r MDS patients and subject to change with longer follow up. Now, after median follow up of 275 days (doubled since May 2024), the mOS among these 14 r/r MDS patients remains strong at 13.4 months, which is significantly longer than the 5-6 months typically expected with standard care, as reported in the literature. Median time on treatment for r/r MDS in the BEXMAB trial at the moment is 7.9 months, exceeding any prior expectations in this field. The treatment remains well tolerated according to the latest safety follow up.

Previously there were two (2/14) patients who moved on to receive bone marrow transplant and there are now a total of three patients (3/14) who have moved to bone marrow transplant which is seen as the only possibility for curative treatment of r/r MDS.

**Business Update / Partnering Discussions**

In June 2024, Faron completed a fully subscribed EUR 30.7 million share offering and published its focus areas for 2024:

1. To obtain regulatory feedback from the USA Food and Drug Administration (FDA) regarding measures required to obtain regulatory approval in the U.S.
2. Aim to complete BEXMAB Phase II enrolment.
3. Aim to conclude a global partnership deal to fund Phase III clinical research and to commercialize *bexmarilimab*.
4. To have sufficient funding until the latter half of March 2025, allowing the Company to pursue readiness to move to Phase III in drug development, and in compliance with the financial covenants of the IPF Fund II SCA, SICAV-FIAR's Facilities Agreement.

In July, Faron obtained positive feedback from the FDA regarding the registrational study plan for *bexmarilimab* in relapsed and refractory high risk MDS (HR MDS). In August 2024, the FDA granted Fast Track Designation (FTD) for *bexmarilimab* for the treatment of r/r MDS. Based on the FDA's guidance, Faron made the decision to recruit additional frontline MDS patients. Full BEXMAB enrolment will include 32 r/r MDS patients and also 20 frontline HR MDS patients. According to the latest enrolment estimate, the BEXMAB trial (including also 20 frontline HR MDS patients) will be fully recruited in January 2025.

Since the fundraising completed in June 2024, Faron has been in dialogue with several partner candidates to fund Phase III development and to commercialize *bexmarilimab*. These discussions have progressed according to Faron's expectations. To date, the Company has chosen not yet to enter into a partnership agreement or grant exclusivity to any negotiating party. Faron continues to discuss and evaluate the received terms and their impact diligently. To enable more flexibility in pursuing the best commercial outcome for the Company and its shareholders in continued compliance with the financial covenants and to facilitate availability of high-quality Phase II BEXMAB efficacy data (also observing patient enrolment for full Phase II readout), Faron may, subject to market conditions, consider strengthening its financial position before concluding discussions

concerning partnering.

### **Scientific Advisory Board Renewed**

Faron has renewed its Scientific Advisory Board (SAB) to better correspond with the Company's current drug development pipeline. The new Scientific Advisory Board consists of prestigious and internationally recognized clinical scientists with broad anti-cancer clinical development expertise within haematological neoplasms and solid tumors. The SAB will assist Faron's management in making significant scientific judgements related to translational activities as well as its clinical portfolio. The members of Faron's SAB are Dr. Toni Choueiri, Dr. Tom Powles, Dr. Amer Zeidan, Dr. Naval G. Daver, Dr. Mika Kontro and Dr. Christophe Massard.

**Toni Choueiri, MD** is the Jerome and Nancy Kohlberg Chair and Professor of Medicine at Harvard Medical School, Boston, MA, the Director of the Lank Center for Genitourinary (GU) Oncology and co-leader of the Kidney Cancer Program at Dana-Farber/Harvard Cancer Center. He serves on the US National comprehensive cancer network (NCCN) expert panel. He has over 800 PubMed-indexed publications and is the lead investigator in multiple international phase 1-3 clinical trials in genitourinary cancers. In a series of NEJM articles on which Dr Choueiri was either first or last author, he has made seminal observations leading to multiple FDA and EMA approvals.

**Tom Powles, MBBS, MRCP, MD** is a professor of urology cancer at the University of London and the Director of Barts Cancer Centre which is one of the UKs largest Cancer Centres. Prof Powles is also editor-in-chief of Annals of Oncology, the leading European oncology scientific journal. He has had a major role in the development of biomarkers and new drug strategies leading to multiple FDA and EMA approvals. He has authored 10 NEJM or Lancet publications with two first author NEJM publications and two first author Nature publications. He was named in December 2023 in TIME's list among the most influential people in global health.

**Amer Zeidan, MD, MBBS, MHS** is an Associate Professor of Medicine, Chief of Hematologic Malignancies Division, Director of Hematology Early Therapeutics Research, and leader of the clinical program and the Clinical Research Team for Leukemia and Myeloid Malignancies at Yale Cancer Center. Dr. Zeidan specializes in the management of myeloid malignancies especially MDS and acute myeloid leukemia (AML). His research and clinical care focus on targeting therapies to a patient's diagnosis and working with their own immune system to counter the malignancies. He has published over 330 peer-reviewed publications and is the principal investigator on numerous phase II and III clinical trials in the areas of acute myeloid leukemia and myelodysplastic syndromes.

**Naval G. Daver, MD** is a Professor and Director of the Leukemia Research Alliance Program in the Department of Leukemia at MD Anderson Cancer Center (MDACC) in Houston, TX. He is a clinical investigator with a focus on molecular and immune therapies in acute myeloid leukemia (AML) and myeloid disease and is principal investigator on more than 25 ongoing institutional, national, and international clinical trials in these diseases, including multiple registration and label enabling trials. Prof. Daver has published over 400 peer-reviewed manuscripts and is on the editorial board of numerous hematology journals.

**Mika Kontro, MD, PhD** is an adjunct professor and a consultant in clinical hematology at the Helsinki University Hospital Comprehensive Cancer Center. Dr. Mika currently works as K. Albin Johansson Cancer Research Fellow (Finnish Cancer Institute) and as a group leader in Finnish Institute of molecular medicine, FIMM. He has a strong background in running clinical trials and he currently chairs the Finnish AML group and is a board member of the Nordic AML Group.

**Christophe Massard, MD, PhD** is professor and a Head of Cancer Research at Gustave-Roussy, the first leading cancer hospital in Europe and in the top four in the world. Dr. Christophe is a member of ESMO, ASCO and AACR and has participated in over 130 trials in the past five years. He has been the principal investigator over the last 10 years of 50 phase 1 trials and co-investigator in more than 100 trials. His research focuses on early clinical trials and precision medicine. He has published over 100 peer-reviewed publications.

### **Development Plan for Solid Tumors Progressing**

Faron has made significant progress with its development plan regarding *bexmarilimab*'s future potential in treating solid tumors. In today's CMD, Faron will present its oncology pipeline for solid tumors to illustrate *bexmarilimab*'s potential as a first-in-class macrophage reprogrammer in various anti-cancer treatments. In addition, an update on the innovative approaches in improving recognition of tumor cells and preventing immunosuppression will be presented.

#### **Dr. Juho Jalkanen, CEO of Faron, comments:**

"As previously communicated, everything is progressing as planned and our focus is to ensure that we are armed with adequate resources to be able to meet our objectives of completing Phase II of the BEXMAB trial and optimizing the outcome of partnering with Phase II data. The next business decision we make will be crucial in how the value and future of *bexmarilimab* is divided. There is more than two decades of hard work behind the development of *bexmarilimab*, and our job is to see that the maximum potential of *bexmarilimab* comes to life for both patients and investors."

#### **Dr. Patri Bono, CMO of Faron, comments:**

**Dr. Paul Bone, CEO of Faron, comments:**

"We've continued to see extremely encouraging data from our ongoing BEXMAB trial, and I am very pleased to see that the data encourage us systematically as we go forward in our solid tumor development pipeline. Our purpose is to establish *bexmarilimab* as a cornerstone drug for cancers where Clever-1 macrophages are a source of treatment resistance and cancer progression. Now we've a world-leading Scientific Advisory Board supporting us, the likes of which I have never seen before, and I am very excited about what future holds."

**Presentation Materials and Webcast**

The Capital Markets Day presentation material will be available at <https://www.faron.com/investors>. The CMD webcast can be followed online at <https://faron.videosync.fi/cmd-2024>

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**About BEXMAB**

The BEXMAB study is an open-label Phase I/II clinical trial investigating *bexmarilimab* in combination with standard of care (SoC) in the aggressive hematological malignancies of acute myeloid leukemia (AML) and myelodysplastic syndrome (MDS). The primary objective is to determine the safety and tolerability of *bexmarilimab* in combination with SoC (azacitidine) treatment. Directly targeting Clever-1 could limit the replication capacity of cancer cells, increase antigen presentation, ignite an immune response, and allow current treatments to be more effective. Clever-1 is highly expressed in both AML and MDS and associated with therapy resistance, limited T cell activation and poor outcomes.

**About *bexmarilimab***

*Bexmarilimab* is Faron's wholly owned, investigational immunotherapy designed to overcome resistance to existing treatments and optimize clinical outcomes, by targeting myeloid cell function and igniting the immune system. *Bexmarilimab* binds to Clever-1, an immunosuppressive receptor found on macrophages leading to tumor growth and metastases (i.e. helps cancer evade the immune system). By targeting the Clever-1 receptor on macrophages, *bexmarilimab* alters the tumor microenvironment, reprogramming macrophages from an immunosuppressive (M2) state to an immunostimulatory (M1) one, upregulating interferon production and priming the immune system to attack tumors and sensitizing cancer cells to standard of care.

**About Faron Pharmaceuticals Ltd**

Faron (AIM: FARN, First North: FARON) is a global, clinical-stage biopharmaceutical company, focused on tackling cancers via novel immunotherapies. Its mission is to bring the promise of immunotherapy to a broader population by uncovering novel ways to control and harness the power of the immune system. The Company's lead asset is *bexmarilimab*, a novel anti-Clever-1 humanized antibody, with the potential to remove immunosuppression of cancers through reprogramming myeloid cell function. *Bexmarilimab* is being investigated in Phase I/II clinical trials as a potential therapy for patients with hematological cancers in combination with other standard treatments. Further information is available at [www.faron.com](http://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

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 addition, other factors which could cause actual results to differ materially include the ability of the Company to successfully license its programs 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.

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