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Faron Pharmaceuticals Oy
27 November 2024

Faron Pharmaceuticals Ltd.

("Faron" or "the Company")

Inside Information: Faron Announces Positive Phase 2 Interim Results from BEXMAB Trial to be presented at ASH

Company announcement, Inside Information, 27 November 2024

Key highlights

- Interim Phase 2 read-out from the BEXMAB Trial confirms earlier positive Phase 1 & 2 findings in MDS patients with prior HMA failure
- In Phases 1 & 2, 20 MDS patients who are refractory or relapsed on HMA (r/r MDS) and have no effective treatment options, continue to show high objective response rate (ORR) at 80%
- The BEXMAB Phase 1 & 2 MDS patients with prior HMA failure are experiencing an estimated median overall survival (mOS) of approximately 13.4 months currently, compared to the 5-6 months that would typically be expected under standard of care historically

TURKU, FINLAND- Faron Pharmaceuticals Ltd. (AIM: FARN, First North: FARON), a clinical-stage biopharmaceutical company focused on tackling cancers via novel immunotherapies, today provides Interim Phase 2 results of the ongoing BEXMAB trial in myelodysplastic syndrome (MDS) patients that have failed a hypomethylating agent (HMA), also known as relapsed/refractory MDS (r/r MDS). Full analysis of the data will be presented at the 66th American Society of Hematology (ASH) Annual Meeting on 9 December 2024 in San Diego, US.

The initial BEXMAB Phase 2 results have already indicated a high ORR of 79% (11/14) amongst HMA-failed MDS patients treated with a combination of *bexmarilimab* + azacitidine. There is now a total of 20 HMA-failed MDS patients evaluable for read-out with this novel combination. The treatment has been well tolerated, without any dose-limiting toxicity. The ORR in this otherwise untreatable population is 80% (16/20). Similar size patient cohorts treated with existing alternatives have reported 0-20% ORR, without deep and durable remissions. The estimated median overall survival of the 20 r/r MDS patients remains 13.4 months.

In summary, the updated BEXMAB results show very encouraging efficacy and robust treatment benefit for the r/r MDS patients. The detailed efficacy, safety and biomarker results of the 20 r/r MDS patients treated in the BEXMAB trial will be presented at the 66th American Society of Hematology Annual Meeting. The BEXMAB trial is continuing to enroll patients as planned with the next efficacy data readout for the fully recruited BEXMAB trial patients expected around the end of Q1 2025.

Dr. Petri Bono, Chief Medical Officer of Faron, said: "r/r MDS is a life-threatening haematological malignancy with limited treatment options and high unmet medical need. Our updated trial results in r/r MDS further enforces *bexmarilimab's* ability to overcome treatment leading to clinically meaningful deep responses. We look forward to sharing the detailed results with the haematology community and discussing these data with health authorities in H1 2025."

Dr. Juho Jalkanen, Chief Executive Officer of Faron, said: "It is remarkable seeing the ORR continuing to be so strong even as the patient population grows, as it would typically be expected to settle at a lower level. For patients, I believe these results are truly exciting as we take another step closer to providing an additional option for their poorly met treatment needs. With our repeatedly strong data, we are very much looking forward to our continuing discussions with regulatory agencies and partner candidates."

Faron will be hosting a virtual webinar to discuss the full analysis of data on Tuesday, December 10, 2024 at 16.00 EET/9am ET.

To register for the event visit: BEXMAB Study Update

The ASH Annual Meeting will take place from 7-10 December 2024, in San Diego, California and virtually. The poster will contain updated clinical data from the trial.

Poster presentation details:

Title:	Encouraging Efficacy of Bexmarilimab with Azacitidine in Relapsed or Refractory MDS in Bexmab Ph1/2 Study
Session Time:	Monday, 9 December 2024, 6:00 PM - 8:00 PM PST
Session Title:	Acute Myeloid Leukemias: Investigational Drug and Cellular Therapies: Poster III

Location:	San Diego Convention Center, Halls G-H
Lead Authors:	Dr. Mika Kontro, MD, PhD, Associate Professor at the University of Helsinki; Dr. Naval Daver, MD, Associate Professor of Leukemia at The University of Texas MD Anderson Cancer Center
Abstract Number:	4265

The full poster will be available on the Company's website at https://www.faron.com/investors once presented at ASH.

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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.

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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