RNS Number : 4011P
Faron Pharmaceuticals Oy
10 December 2024

Faron Pharmaceuticals Ltd.

("Faron" or "the Company")

Faron Presents Full Analysis of Positive Phase 2 Interim Data from BEXMAB Trial at the 66th American Society of Hematology (ASH) Annual Meeting

Press release, 10 December 2024

Poster highlights

- Overall response rate of 80% (16 out of 20) in refractory or relapsed HMA failed MDS patient population (r/r MDS)
- Observed responses were primarily deep and durable with 70% (14 out of 20) r/r MDS patients achieving complete response (CR) / marrow complete remission (mCR) / partial response (PR).
- Four patients have moved on to receive a bone marrow transplant
- Estimated median overall survival (mOS) of approximately 13.4 months in r/r MDS population
- The combination of *bexmarilimab* and azacitidine remains well tolerated
- Clever-1 target engagement and expression in the bone marrow with an increased antigen presentation capacity and presence of CD8 T and NK cells supports *bexmarilimab* mechanism-of-action
- Webinar scheduled today at 16.00 EET/9am ET/6am PT (please see link to register below)

TURKU, FINLAND- Faron Pharmaceuticals Ltd. (AIM: FARN, First North: FARON), a clinical-stage biopharmaceutical company focused on tackling cancers via novel immunotherapies, today announced full analysis of the positive Phase 2 interim readout presented at the 66th American Society of Hematology (ASH) Annual Meeting and Exposition.

"The BEXMAB results continue to improve over time showing a remarkable 80% ORR in r/r MDS patients," **said Dr. Juho Jalkanen, Chief Executive Officer of Faron** "The combination is well-tolerated and generates strong and durable cancer blast reduction and hematological improvements. This solidifies *bexmarilimab's* unique and leading mechanism of action for the treatment of MDS and in the field of myeloid cell re-programming. With this compelling evidence, we are well positioned to advance to the full Phase 2 efficacy readout and actively pursue further regulatory interactions to navigate and refine the pivotal pathway for BLA filing."

Dr. Mika Kontro, MD, PhD, Associate Professor at the Helsinki University Hospital Comprehensive Cancer Center and Principal Investigator of the BEXMAB trial, said "Addressing MDS remains a considerable therapeutic challenge due to the limited efficacy of the current standard of care, particularly in *TP53* mutated and HMA-failed MDS patient populations. The data presented at ASH are highly promising, showing notable improvements in overall response rate and overall survival. These findings highlight the meaningful strides Faron is making in improving treatment outcomes for r/r MDS."

The BEXMAB study is a multicenter study, taking place in Finland, UK and the U.S., evaluating the safety and efficacy of *bexmarilimab*, a novel anti-Clever-1 humanized antibody, with standard of care in patients with aggressive myeloid leukemias.

Faron will host a virtual webinar to discuss the full analysis of data today, 10 December 2024 at 16.00 EET/9am ET/6am PT.

To register for the event visit: BEXMAB Study Update

The ASH Annual Meeting takes place from 7-10 December 2024, in San Diego, California and virtually.

ASH 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 PT

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 is available on the Company's website at https://www.faron.com/investors and contains updated clinical data from the BEXMAB trial.

For more information please contact:
ICR Healthcare
Mary-Jane Elliott, David Daley, Lindsey Neville
Phone: +44 (0)20 3709 5700
E-mail: faron@icrhealthcare.com

Cairn Financial Advisers LLP, Nomad
Sandy Jamieson, Jo Turner
Phone: +44 (0) 207 213 0880

Peel Hunt LLP, Broker
Christopher Golden, James Steel
Phone: +44 (0) 20 7418 8900

Sisu Partners Oy, Certified Adviser on Nasdaq First North
Juha Karttunen
Phone: +358 (0)40 555 4727
Jukka Järvelä
Phone: +358 (0)50 553 8990

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 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

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.

END

NRAFLFFDFFLAIIS