Faron Pharmaceuticals Ltd | Company announcement | August 18, 2025 at 09:00:00 EEST

Inside Information: Accelerated approval pathway confirmed for frontline patients with CR + CReq, and Overall Survival as primary endpoints

TURKU, FINLAND â€“ Faron Pharmaceuticals Ltd. (AIM: FARN, First North: FARON), a clinical-stage biopharmaceutical company focused on tackling cancers through novel immunotherapies, today announces it has received positive and valuable feedback from the U.S. Food and Drug Administration (FDA) regarding the proposed clinical development plan leading to approval for *bexmarilimab*, its wholly-owned, novel precision cancer immunotherapy.

The feedback was received as part of the Companyâ€™s recent BEXMAB studyâ€™s end-of-phase 2 (EOP2) meeting with the FDA. The FDA advised Faron to focus on frontline development since possible frontline approval enables use across the entire HR MDS indication. The meeting was requested to gain alignment on the design of a planned registrational phase 2/3 trial evaluating *bexmarilimab* in combination with azacitidine for patients with treatment-naÃ¯ve (frontline) higher-risk myelodysplastic syndrome (HR-MDS). Key objectives included obtaining the FDAâ€™s input on the proposed trial design, dosing strategy and clinical endpoints intended to support regulatory approval.

Following the FDA's guidance, the trial will begin with a dose optimisation run-in period comparing 1 mg/kg and 3 mg/kg regimens with placebo, all in combination with azacitidine. Once the optimal dose has been determined, the trial will seamlessly transition into the registrational stage, which includes an interim analysis to support accelerated approval based on IWG 2023 response criteria in frontline patients.

â€œWe are extremely encouraged by the collaborative and highly productive dialogue with the FDA, which provided a clear and actionable path for the clinical development of *bexmarilimab* in frontline HR-MDS, an area of profound unmet medical need,â€ **said Dr. Juho Jalkanen, Chief Executive Officer of Faron.** â€œThe agencyâ€™s guidance has endorsed a direct route towards accelerated approval using Complete Response (CR) + CR equivalent (CReq) per International Working Group (IWG) 2023 criteria as a co-primary endpoint with Overall Survival (OS). This is a significant step forward in our mission to provide a potentially transformative new treatment option to patients and represents a major regulatory de-risking milestone, as we are now only one study away from getting bexmarilimab approved for the benefit of HR MDS patients.â€

The FDA confirmed IWG 2023-defined CR + CReq as an acceptable primary endpoint to support an application for accelerated approval in frontline patients. In line with this guidance, Faron will include CR + CReq as a co-primary efficacy endpoint along with Overall Survival (OS) in the phase 2/3 trial. The Company will seek accelerated approval based on an interim readout on the CR + CReq data in frontline patients. Composite complete remission (cCR) will be evaluated as the key secondary endpoint. In addition to the clinical discussion, the FDA was satisfied with Faronâ€™s approach to non-clinical and CMC activities for phase 2/3 and subsequent steps to approval.

â€œImproving outcomes of patients with HR-MDS continues to be a top priority for our field. Bexmarilimab is an antibody with a novel mechanism of action that has demonstrated promising safety and activity in combination with azacitidine in phase 1/2 clinical trials in the first- and second-line settings for HR-MDS,â€ added Dr. Amer Zeidan, MBBS, MHS, Professor of Medicine at Yale School of Medicine and Chief of the Division of Hematologic Malignancies at Yale Cancer Center and Smilow Cancer Hospital. â€œI am thrilled that we have agreed with the regulators on a pathway to explore the full potential of *bexmarilimab* in the frontline setting for patients with HR-MDS. I also would like to highlight the FDA accepting the use of CR+CReq IWG 2023 criteria as part of the primary endpoint, making this the first registrational clinical trial to do so. Many experts, including myself, strongly believe the IWG 2023 criteria to be more patient centric and reflect clinically meaningful benefits to patients in a more robust fashion than the old IWG 2006 criteria, which have been used for all past (and failed) phase 3 clinical trials for HR-MDS,â€ concluded Dr. Zeidan.

Disclosure: Dr Amer Zeidan has consulted and received honoraria from Faron. The views expressed as his personal views and not necessarily those of his employer.

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About BEXMAB

The BEXMAB study is an open-label Phase I/II clinical trial investigatingÂ *bexmarilimab*Â 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 ofÂ *bexmarilimab*Â 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.

AboutÂ *bexmarilimab*
*Bexmarilimab*Â is Faronâ€™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.Â *Bexmarilimab*Â 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,Â *bexmarilimab*Â 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 Companyâ€™s lead asset isÂ *bexmarilimab*, a novel anti-Clever-1 humanized antibody, with the potential to remove immunosuppression of cancers through reprogramming myeloid cell function.Â *Bexmarilimab*Â 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 atÂ 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 â€believeâ€, â€couldâ€, â€œshouldâ€, â€œexpectâ€, â€œhopeâ€, â€œseekâ€, â€envisageâ€, â€estimateâ€, â€intendâ€, â€mayâ€, â€planâ€, â€potentiallyâ€, â€willâ€ 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 Directorsâ€™ current expectations and assumptions regarding the Companyâ€™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 Directorsâ€™ 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.