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Faron Pharmaceuticals Ltd.

("Faron" or the "Company")

Inside Information: FDA Grants Fast Track Designation for *Bexmarilimab* in r/r MDS

Company announcement, Inside Information, 26 August 2024 at 7:00 a.m. BST / 9:00 a.m. EEST

Key highlights

- Given the strong data seen in Phase 1 and continuing in Phase 2 of Faron's BEXMAB trial, the FDA has granted Fast Track Designation (FTD) for *bexmarilimab* for the treatment of r/r MDS
- FTD further strengthens the *bexmarilimab* program by offering clinical development and commercialization benefits

TURKU, Finland - Faron Pharmaceuticals Ltd. (AIM: FARN, First North: FARON), a clinical-stage biopharmaceutical company pursuing a CLEVER-1 receptor targeting approach to reprogramming myeloid cells to activate anti-tumor immunity in hematological and solid tumors, today announces that their lead candidate *bexmarilimab* has been granted Fast Track Designation for the treatment of relapsed or refractory myelodysplastic syndrome (r/r MDS) in combination with azacitidine by the USA Food and Drug Administration (the FDA).

Fast Track Designation is granted by the FDA for products that are intended for the treatment of serious or life-threatening disease or conditions, which demonstrate the potential to address an unmet medical need. The designation offers the opportunity for frequent interactions with the FDA to discuss the drug's development plan and ensure collection of appropriate data needed to support drug approval, as well as eligibility for rolling submission of a New Drug Application.

Given the previously reported promising results in both Phase 1 and 2 of Faron's BEXMAB trial when treating r/r MDS patients using a combination of bexmarilimab and azacitidine to overcome primary or developed resistance to azacitidine, *bexmarilimab* has been granted Fast Track Designation subsequent to the accelerated development plan proposed by the FDA in July 2024. "This news highlights the urgency for new treatment options besides HMAs for the treatment of higher-risk MDS and solidifies our case that *bexmarilimab* can overcome resistance to HMAs", says Dr. Juho Jalkanen CEO of Faron. Relapsed or refractory myelodysplastic syndrome is an aggressive and deadly form of blood cancer, for which there is very limited treatment option and a median survival of only 5-6 months. The standard of care for higher-risk MDS is azacitidine or another hypomethylating agent (HMA). Unfortunately, the majority of patients eventually relapse or are non-responsive to HMAs, which then leads to r/r MDS. Currently around 180,000 - 510,000 people globally live with an MDS diagnosis.

"r/r MDS is a serious life-threatening condition with limited treatment options and therefore highly significant unmet medical need. Our trial results to date in hypomethylating agent (HMA)-failed MDS have shown *bexmarilimab's* efficacy to induce deep, clinically meaningful responses for these patients. This FDA Fast Track Designation significantly strengthens *bexmarilimab's* position to become a new cornerstone treatment of r/r MDS and will facilitate the development of *bexmarilimab* for full market approval in r/r MDS. It also represents a significant additional recognition of the potential of myeloid cell reprogramming in overcoming resistance and activating immune system in the treatment of various hematological and solid tumors" says Dr. Bono, the CMO of Faron.

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About BEXMAB
The BEXMAB study is an open-label Phase 1/2 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 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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