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Faron Pharmaceuticals Ltd.

("Faron" or "the Company")

Faron Announces Positive Update on Recent Interactions with UK Regulatory Authorities regarding *bexmarilimab* and expanding the BEXMAB Study to the UK

- MHRA has awarded *bexmarilimab* an Innovation Passport for the treatment of relapsed/refractory Myelodysplastic Syndrome and given approval for the BEXMAB trial to be conducted in the UK
- UK sites to join the BEXMAB Study iminently

Press release, 2 December 2024

TURKU, FINLAND- Faron Pharmaceuticals Ltd. (AIM: FARN, First North: FARON), a clinical-stage biopharmaceutical company focused on tackling cancers via novel immunotherapies, today announces that the BEXMAB Study may proceed in the UK and *bexmarilimab* has received an Innovation Passport, under the Innovative Licensing and Access Pathway (ILAP) from the UK's Medicines and Healthcare products Regulatory Agency (MHRA), for the treatment of relapsed/refractory Myelodysplastic Syndrome (r/r MDS).

The ILAP was introduced by the MHRA in 2021 to give patients quicker access to cutting-edge treatments and therapies for life-threatening or seriously debilitating conditions, or conditions for which there is a significant patient or public health need. The benefits of the ILAP include enhanced regulatory support from the MHRA and provides collaborative opportunities with health technology assessment bodies and other stakeholders, with the aim of accelerating the development, and improving patient access to promising new medicines.

The decision to award the Innovation Passport to *bexmarilimab* was made by the ILAP Steering Group, which is comprised of representatives from the MHRA, NICE, AWTTC and SMC, and provides further regulatory verification of *bexmarilimab's* potential to address significant unmet medical needs and positions the therapy for faster development and potentially earlier access for patients.

In addition, Faron today announced that it has received regulatory approval from the MHRA to conduct the BEXMAB trial in the UK. This approval will allow Faronto recruit UK haematology patients directly, accelerating its research efforts by increasing recruitment and enhancing the study's diversity and scope by expanding the participant pool.

Dr. Juho Jalkanen, Chief Executive Officer of Faron, said "I am very pleased to announce this update today following our ongoing interactions with the MHRA regarding *bexmarilimab. A*t Faron, we understand the importance of actively engaging with regulatory authorities and, as a result of those interactions and the promising data generated to date, I am very pleased that the MHRA has recognised the potential of *bexmarilimab* to treat r/r MDS patients. *R*eceiving ILAP designation, coupled with regulatory approval to conduct the BEXMAB trial in the UK, will allow us to accelerate the development of *bexmarilimab and* give UK patients access to a promising novel therapeutic option through participation in the study. We are looking forward to continuing our discussions with the MHRA to further expedite *bexmarilimab's* path to market for patients as soon as possible."

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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 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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