Faron Pharmaceuticals Oy

("Faron" or the "Company")

Inside Information: Faron Announces Positive US Food and Drug Administration (FDA) Feedback to Progress *Bexmarilimab* as a Monotherapy in Solid Tumors

- Green light for continued clinical development after data package review
- Alignment with company's selection of 1 mg/kg IV once-every-3-weeks (Q3W) as dose for further evaluation
- Supportive of biomarker-driven approach with CLEVER-1 staining of tumor biopsy

Company announcement, March 22, 2023 at 03:00 AM (EDT) / 07:00 AM (GMT) / 09:00 AM (EET)

Inside information

TURKU, FINLAND / BOSTON, MA – Faron Pharmaceuticals Oy (AIM: FARN, First North: FARON), a clinical stage biopharmaceutical company focused on tackling difficult-to-treat cancers, announces positive FDA feedback and recommendations for the future development of *bexmarilimab* as a monotherapy in multiple solid tumors. The agency's advice follows an end-of-Phase I/II meeting this month. The Phase I/II MATINS trial is investigating *bexmarilimab*, Faron's wholly owned precision immunotherapy asset, in multiple cancer indications.

The official meeting minutes are consistent with the FDA's Project Optimus initiative to reform dose optimization and the selection paradigm in oncology drug development, which MATINS sought to comply with through multiple dose and indication arms of the study. FDA provided the following positive meeting feedback which further aligns the agency's views on *bexmarilimab* with the Company's, including:

- Completed toxicology studies are adequate to support further clinical development of single-agent (monotherapy) *bexmarilimab* into a registration trial
- Selection of 1 mg/kg IV Q3W as dose for further evaluation appears reasonable, although additional data are required to establish the recommended Phase II/III dose for specific cancer(s)
- Valuable feedback and guidance on further development of a simple, validated staining assay to identify patients with CLEVER-1 positive tumors for clinical trial inclusion

"We are pleased to have received these positive and supportive FDA recommendations for the continued clinical development of *bexmarilimab* as a monotherapy in solid tumors," said CEO Markku Jalkanen. "As a first-in-human study for *bexmarilimab*, MATINS has laid the groundwork for multiple routes to market."

Faron had previously announced a meeting with the agency would occur this quarter.

"FDA's feedback on the MATINS study gives Faron an excellent roadmap to plot out *bexmarilimab's* future strategy," said Chief Medical Officer Marie-Louise Fjällskog. "We thank the FDA for its time and consideration of our briefing package and anticipate additional fruitful interactions."

This announcement contains inside information for the purposes of Article 7 of Regulation (EU) No 596/2014 ("MAR").

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About MATINS

MATINS has demonstrated a positive safety profile in more than 200 patients treated with *bexmarilimab*. The study has observed an approximate 30% clinical benefit rate in several tumor types, which is associated with an interferon gamma (IFN-y) increase and leads to a significant survival benefit. Moreover, responding patients can be potentially identified using baseline IFN-y or CLEVER-1 expression. CLEVER-1 is a novel immune checkpoint, a receptor shown to promote an immunosuppressive environment.

About Faron Pharmaceuticals Oy

Faron Pharmaceuticals Oy (AIM: FARN, First North: FARON) together with its subsidiaries, is a clinical stage biopharmaceutical group focused on building the future of immunotherapy by harnessing the power of the immune system to tackle cancer and inflammation. *Bexmarilimab*, a novel anti-CLEVER-1 humanized antibody, is its investigative precision immunotherapy with the potential to provide permanent immune stimulation for difficult-to-treat cancers through targeting myeloid function. Currently in Phase I/II clinical development as a potential therapy for patients with hematological cancers and untreatable solid tumors, *bexmarilimab* has potential as a single-agent therapy or in combination with other standard treatments including immune checkpoint molecules. In terms of other pipeline assets, Traumakine® is an investigational intravenous (IV) interferon beta-1a therapy for the treatment of hyperinflammatory conditions. Faron is headquartered in Turku, Finland. 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 particular, the early data from initial patients in the MATINS trial may not be replicated in larger patient numbers and the outcome of clinical trials may not be favorable or clinical trials over and above those currently planned may be required before the Company is able to apply for marketing approval for a product. 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.