Faron Pharmaceuticals Ltd.  
("Faron or “Company”")

Faron Pharmaceuticals Announces Poster Presentation of Targeted Immunotherapy Bexmarilimab at Society for Immunotherapy of Cancer (SITC) 2022 Annual Meeting

Press release, November 2, 2022 at 03:00 AM (EDT) / 07:00 AM (GMT) / 09:00 AM (EET)

TURKU, FINLAND / BOSTON, MA – MA: Faron Pharmaceuticals Ltd (AIM: FARN, First North: FARON), a clinical-stage biopharmaceutical company focused on tackling difficult-to-treat cancers and inflammation via precision immunotherapy, will have a poster outlining the BEXCOMBO clinical trial of its CLEVER-1 antibody bexmarilimab at the Society for Immunotherapy of Cancer’s (SITC) 37th Annual Meeting (2022) in Boston, MA.

Details of the poster presentations are as follows:

Title: Phase II Study to Assess the Safety and Efficacy of the CLEVER-1 Antibody Bexmarilimab in Combination with PD-1 blockade in Patients with Advanced Solid Tumors – BEXCOMBO

Abstract ID: 709

Presenter: Inka Pawlitzky, PhD, Faron

Date/Time: Thursday, November 10, 2022, 9:00 a.m. - 9:00 p.m. ET

The abstract will be provided on the SITC Annual Meeting website at https://www.sitcancer.org/2022/abstracts/abstract-titles-publications and will be available in a Journal for ImmunoTherapy of Cancer (JITC) supplement, which will be published on Nov. 7 at 8 a.m. EST. The poster will also be presented on November 10 at 9 a.m. – 9 p.m. EST

About BEXCOMBO:

BEXCOMBO is a Phase II study that aims to enrol up to 120 patients in a single-arm, multicenter, adaptive design trial. A Simon’s 2-Stage design is planned to evaluate 15 patients in Stage 1 and an additional 25 patients in Stage 2 per indication. The study design includes a safety run-in and allows for enrichment of patient populations based on CLEVER-1 expression level, PD-L1 status or biomarkers predictive of response based on emerging non-clinical and clinical data. The study indications include metastatic or unresectable, recurrent HNSCC, locally advanced or metastatic UCC and metastatic NSCLC where first-line PD-1 blockade is approved standard of care. Enrollment is planned to begin in Q1 2023, with up to 10 clinical trial sites across the US and Europe. The primary objective is to evaluate the clinical efficacy of the combination therapy bexmarilimab plus PD-1 blockade based on objective response rate (ORR) using Response Evaluation Criteria in Solid Tumors (RECIST v1.1).

Clinical data show that 65-80% of cancer patients do not respond to single agent PD-1 blockade and evolving data suggest that IFN-γ expression is required for response to PD-1 blockade. Bexmarilimab induces IFN-γ upregulation, which is required for immune modulation in the tumor microenvironment, T cell activation and ultimately response to PD-1/PD-L1 inhibition therapy. Bexmarilimab ignites the immune response in tumors without preexisting immune activation, and the BEXCOMBO study thereby offers the opportunity to expand the population of responders and provide meaningful benefit to more patients.
About Bexmarilimab:

Bexmarilimab is Faron’s wholly-owned, investigative precision immunotherapy with the potential to provide permanent immune stimulation for difficult-to-treat cancers through targeting myeloid cell function. A novel anti-CLEVER-1 humanized antibody, bexmarilimab targets CLEVER-1 positive (Common Lymphatic Endothelial and Vascular Endothelial Receptor 1) tumor associated macrophages (TAMs) in the tumor microenvironment, converting these highly immunosuppressive M2 macrophages into immune stimulating M1 macrophages. As an immuno-oncology therapy, bexmarilimab has potential as a single-agent therapy or in combination with other standard treatments including immune checkpoint molecules or targeted agents in both solid tumors and hematologic malignancies. Beyond immuno-oncology, it offers potential in infectious diseases, vaccine development and more.

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About Faron Pharmaceuticals Ltd.
Faron (AIM: FARN, First North: FARON) is a clinical stage biopharmaceutical company developing novel treatments for medical conditions with significant unmet needs caused by dysfunction of our immune system. The Company currently has a pipeline based on the receptors involved in regulation of immune response in oncology, organ damage and bone marrow regeneration. 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 solid tumors and hematologic malignancies, bexmarilimab has potential as a single-agent therapy or in combination with other standard treatments including immune checkpoint molecules. Traumakine is an investigational intravenous (IV) interferon beta-1a therapy for the treatment of acute respiratory distress syndrome (ARDS) and other ischemic or hyperinflammatory conditions. Traumakine is currently being evaluated by the 59th Medical Wing of the US Air Force and the US Department of Defense for the prevention of multiple organ dysfunction syndrome (MODS) after ischemia-reperfusion injury caused by a major trauma. Faron is based 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 favourable 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 licence its programmes 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.