



Top line data from the Phase III INTEREST trial

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Faron Pharmaceuticals Ltd
("Faron" or the "Company")

Faron announces top line data from the Phase III INTEREST trial with Traumakine in the treatment of ARDS

- ***INTEREST study did not meet the primary composite end point for efficacy***
- ***Both Traumakine and placebo reported similar all cause mortality rates at day 28 and at day 90, with no difference in the number of ventilator free days***
- ***Further investigations are currently underway to provide additional information on the outcome of the current analysis***

TURKU - FINLAND, 8 May 2018 - Faron Pharmaceuticals Ltd ("Faron") (AIM: FARN), the clinical stage biopharmaceutical company, today announces top line data from its pan-European Phase III INTEREST trial. The INTEREST study did not meet the Day 28 (D28) primary efficacy composite endpoint of ventilator free days and survival with Traumakine treatment.

Treatment with Traumakine did not result in an increased number of ventilator free survival days or a reduced mortality rate when compared to placebo.

- The median number of ventilator free days at Day 28 was 10 days in patients treated with Traumakine and 8.5 days in the placebo group.
- All cause mortality at Day 28, another important efficacy endpoint, was 26.4% for Traumakine and 23.0% for the placebo group.
- At Day 90 all cause mortality in the Traumakine group was 32.6% compared to 31.6% in the placebo group.
- None of these differences were statistically significant.

Safety was continually monitored throughout the study and there were no clinical concerns following the repeated administration of Traumakine.

Dr Markku Jalkanen, CEO of Faron, said: *"We are incredibly disappointed and surprised by these results. We need to further analyse the data in order to understand how this study differs from our previous positive results with ARDS patients, both in terms of Traumakine's efficacy, and in the unusually low mortality rate observed in the placebo arm. We look forward to the results of the Japanese study in Q3 2018 and will be considering how we can advance Traumakine in clinical development."*

"We will continue our plans to advance our next asset, Clevegen, our second candidate which is a ground breaking anti-Cleaver-1 antibody, into clinical development in solid cancers later this year."

"I would like to thank everyone who has been involved in the study including our investigators, study personnel, the team at Faron and, most of all, the patients and their families who participated in the study."

The INTEREST trial was a Phase III double-blind, randomised, parallel-group comparison to assess the efficacy and safety of Traumakine® (FP-1201-lyo) versus placebo in the treatment of patients with moderate to severe Acute Respiratory Distress Syndrome (ARDS). The study, which recruited 300 patients, was conducted in 64 hospital intensive care units (ICU) in Belgium, the Czech Republic, Finland, France, Germany, Italy, Spain and the UK.

ARDS is a severe orphan disease with a reported mortality rate of approximately 30-45%^{[1],[2],[3]}, for which there is currently no approved pharmacological treatment. It is characterised by widespread capillary leakage and inflammation in the lungs, most often as a result of pneumonia (e.g. following a pandemic influenza), sepsis, or significant trauma. Faron estimates there are around 300,000 plus annual cases in Europe and US alone.

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

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About Faron Pharmaceuticals Ltd

Faron (AIM:FARN) is a clinical stage biopharmaceutical company developing novel treatments for medical conditions with significant unmet needs. The Company currently has a pipeline focusing on acute organ traumas, vascular damage and cancer immunotherapy. The Company's lead candidate Traumakine, to prevent vascular leakage and organ failures, has completed a Phase III clinical trial in Acute Respiratory Distress Syndrome (ARDS). An additional European Phase II Traumakine trial is underway for the Rupture of Abdominal Aorta Aneurysm ("RAAA"). Faron's second candidate Clevegen is a ground breaking pre-clinical anti-Clever-1 antibody. Clevegen has the ability to switch immune suppression to immune activation in various conditions, with potential across oncology, infectious disease and vaccine development. This novel macrophage-directed immuno-oncology switch called Tumour Immunity Enabling Technology ("TIET") may be used alone or in combination with other immune checkpoint molecules for the treatment of cancer patients. Faron is based in Turku, Finland. Further information is available at www.faron.com

^[1] JAMA. 2016 Feb;315(8):788-800

^[2] Intensive Care Med. 2011;37(12):1932

^[3] N Engl J Med. 2005;353(16):1685

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