TURKU – FINLAND

Press release on May 9, 2011

Faron reports positive headline data from FPCLI001 clinical study with FP-1201 in acute lung injuries

Faron Pharmaceuticals Ltd. ("Faron") announced today that it has obtained positive headline data from the Phase II part of the clinical study FPCLI001. These data indicate that the use of the FP-1201 dose regimen (six daily doses of 10 microgram/day) in acute lung injury (ALI) and its more severe form Acute Respiratory Distress Syndrome (ARDS)

- was well tolerated
- significantly reduced the all cause mortality in patients at day 28

The FPCLI001 study consisted of two parts. The first part of this clinical trial tested the safety and tolerability of escalating doses of FP-1201 in patients with ALI/ARDS. This part of the study was successfully completed in August 2010 and identified the optimal tolerated dose (OTD) of FP-1201, as 10 microgram/day. This dose was subsequently used in the second part of the study in which 22 patients were treated. The 10 microgram/day dose administered for a maximum of six days was well tolerated and no drug related toxicity was observed.

The primary efficacy end point of the study was all cause mortality at day 28. This is the only primary efficacy end point accepted by the European Medicines Agency (EMA) that can be used to obtain regulatory approval for products to treat ALI/ARDS. In the first part of the study only one patient died (in the lowest dose cohort) out of a total of 15 patients. This part of the data will be presented as a poster (#17742) at the Annual American Thoracic Society (ATS) Meeting in Denver (Co, USA) on May 15th, 2011.

In the second part of the study only two out of 22 recruited patients died (both with multiple organ failure). Therefore, the total mortality of the FPCLI001 study was three out of 37, or 8.1 %. The overall mortality of patients with ALI/ARDS is between 35-45 % and the total number of annual ALI/ARDS patients in Europe is close to 200.000 (see references below).

The whole study also included assessment of several biomarkers as surrogates to elucidate the mechanism of action of FP-1201. The company expects these results to become available by the end of Q3-2011.

“Two of the early pathophysiological events in ALI/ARDS that affect lung function are vascular leakage and escalation of inflammation. Both these events can be modulated by locally active adenosine, the enzymatic end product of the FP-1201 target gene CD73”, says Dr. Geoff Bellingan from University College London Hospitals (UCLH), who also is the Principle Investigator of the FPCLI001

study. “The results of the FPCLI001 study support the hypothesis that modulation of vascular leak and inflammation may reduce mortality in ALI/ARDS”, comments Dr. Bellingan.

About ALI/ARDS and FP-1201 (human recombinant interferon-beta 1a)
ALI and ARDS are serious clinical disorders, which follow a variety of severe direct and indirect lung insults. In serious life threatening situations such as infection leading to sepsis or trauma causing massive tissue injury, an escalation of the systemic inflammatory response leads to multiple organ failure including ALI/ARDS. In the case of ALI/ARDS the predominant patho-physiological result is increased vascular leakage, which has been shown to be due to the lack of adenosine, an end product of AMP degradation by 5’-nucleotidase (CD73). Adenosine acts to enhance endothelial barrier function via adenosine receptor activation. Therefore, any biological substance, which acts to increase adenosine level, will reduce vascular leakage and be of benefit in ALI/ARDS patients. Such substances are type I interferons, and especially the interferon-beta (IFN-beta). IFN-beta has been shown to up-regulate 5’-nucleotidase (also known as a CD73 molecule and expressed abundantly by normal endothelial cells) and prevent ALI in animal models (Kiss et al. (2007) *Eur. J. Immunol.* 37:3334). IFN-beta is therefore a potential treatment for ALI/ARDS. The schematic drawing below (Figure 1) illustrates this principle.

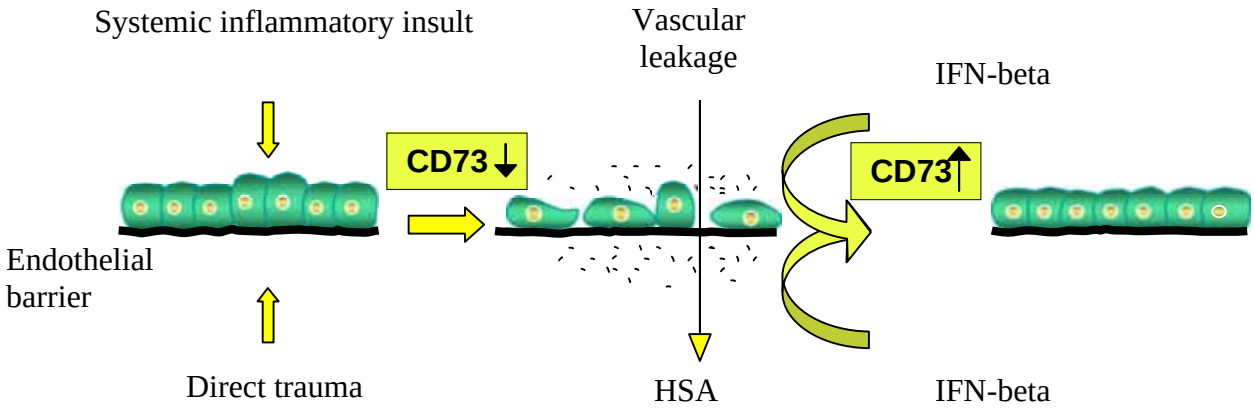

Figure 1: A model of IFN-beta action in acute injuries and prevention of vascular leakage

Faron has been granted an orphan drug status for the treatment of ALI/ARDS with interferon-beta by European Commission and European Medicines Agency (EMEA) under the registration number EU/3/07/505. Faron has also been granted several patents both in USA and Europe, and has several pending applications in other territories for this new use of IFN’s to treat various ischemic conditions. The medical need for an effective and safe treatment of ALI/ARDS is high, since this condition is life threatening with 35-45 % mortality rate (Rubenfeld et al. (2005) *N Engl J Med* 353, 1685) (Phua et al. (2009) *Am J Respir Crit Care Med* 179, 220) and affects close to 200.000 patients in Europe

alone. Currently no approved pharmacological treatment of ALI/ARDS by the regulatory authorities in Europe (EMA) or in the USA (FDA) is available.

About Faron Pharmaceuticals

Faron Pharmaceutical Ltd. is a privately owned clinical stage drug discovery and development company in Turku, Finland. Today Faron has three major drug development projects focusing on acute trauma, incipient vasculopathies, inflammatory diseases, and cancer/metastasis growth.

Faron's lead product FP-1201 is currently being assessed in a phase I/II study in the UK to treat vascular leakage in ALI/ARDS patients. In addition, Faron is currently expanding the FP-1201 program to a pan-European pivotal phase III study that company hopes to get started in 2012. The primary efficacy endpoint in this study will be all cause mortality at day 28.

For more information on the company, please visit:
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