



Press Release

June 11, 2008

FARON INITIATES PHASE I/II CLINICAL TRIAL IN UK TO TREAT ACUTE LUNG INJURY

The UK Medicines and Healthcare products Regulatory Agency (MHRA) has approved Faron's clinical trial application (CTA) for acute lung injury (ALI). According to the letter from the MHRA Faron can initiate a phase I/II clinical study with the Faron's lead drug candidate FP-1201 in ALI patients. Faron expects that the study will now commence immediately. FP-1201 is interferon-beta that prevents leakage of vascular beds in injured organs or at traumatic sites of various tissues. ALI develops following direct or indirect insults to the lungs. It is an especially deadly condition that occurs following vascular leakage, which then results in severe respiratory failure.

The clinical study has two parts. The first one tests safety and tolerability with increasing doses of FP-1201 and the second the initial efficacy of the product. The study has been planned according to the European Medicines Agency (EMA) guidelines for ALI, which became effective on first of April 2007. According to these guidelines the primary end point for ALI/ARDS is all cause mortality at the day 28. The overall mortality of patients with ALI is between 35-40 % and today there are no approved pharmacological treatments for ALI. The mainstay of treatment for ALI at the moment is mechanical ventilation and the treatment of associated infections. The study will be performed at three different London hospitals, the University College London Hospital being the lead site. Dr. Geoff Bellingan will be the Principal Investigator of the study that is planned to be finished during 2009.

- We are very excited about this approval as it follows pretty much those time lines we set up for ourselves when we decided to go to clinic with FP-1201, says Faron's President and CEO **Markku Jalkanen**. This open study will provide us with important safety data but also initial efficacy as we advance with patient enrolment, continues Jalkanen. We will use this experience to design the final pivotal clinical study in order to be able to file a marketing authorization application, which we have targeted to take place during 2011-12, finishes Jalkanen

About ALI and Traumakine®-program

Acute Lung Injury (ALI) and a related condition Acute Respiratory Distress Syndrome (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 injuries, an escalation of the systemic inflammatory response leads to multiple organ failure including ALI/ARDS. In the case of ALI/ARDS the predominant pathophysiological result is increased vascular leakage, which has been shown to be

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due to the lack of adenosine, an end product of AMP degradation by 5'-nucleotidase. 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. 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 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.

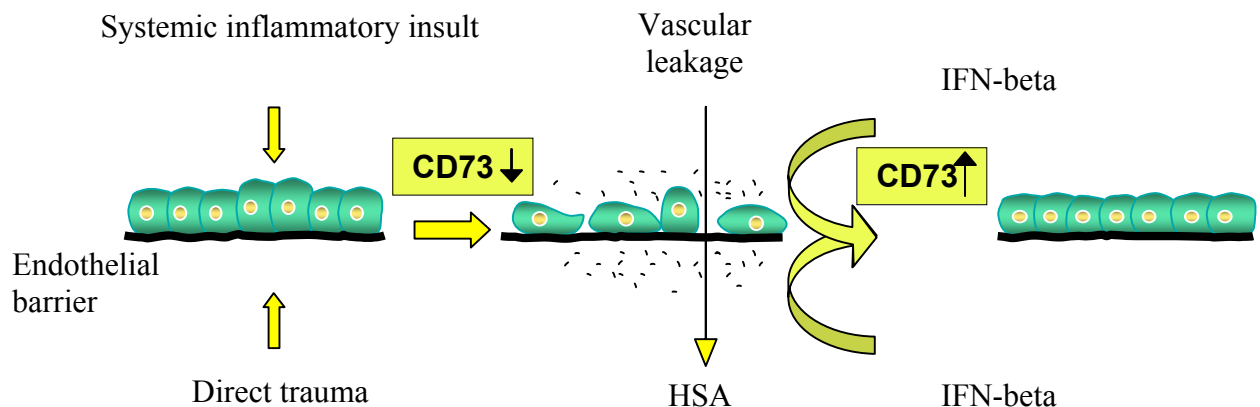


Figure 1: A model of IFN-beta action in acute injuries and prevention of vascular leakage

Faron has been granted an orphan drug status for Traumakine (FP-1201) in ALI/ARDS by European Commission and European Medicines Agency (EMA) under the registration number EU/3/07/505 and has a pending application in USA.

About Faron Pharmaceuticals

Faron Pharmaceuticals, Ltd. is a virtual drug development company with three major drug development targets focusing on indications such as acute traumas, incipient vasculopathies, inflammatory diseases and cancer metastasis.

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