



Press release for immediate publishing

Rentschler to manufacture Faron product Traumakine®

Turku, Finland and Laupheim, Germany – January 17th, 2011. Faron Pharmaceuticals Ltd. and Rentschler Biotechnologie GmbH announced today that they have signed a manufacturing and supply agreement for the Faron product FP-1201 that is also known as **Traumakine®**. The active pharmaceutical ingredient of the FP-1201 is recombinant human interferon beta-1a (IFN-beta 1a) that was first produced by Rentschler already in the late 1980's. According to the agreement Rentschler will become the sole global manufacturer of IFN-beta 1a for Faron and also manufacture Faron's proprietary bulk drug product. Traumakine® is formulated so that it is stable at room temperature and readily available for critical care doctors at intensive treatment units. Traumakine® is meant to prevent vascular leakage in patients with acute lung injuries (ALI) and its more severe form ARDS. This prevention is critical to sustain respiratory function in ALI/ARDS patients. Financial details of the agreement were not disclosed.

- Our aim is to build a specialty pharma product for critical care doctors treating ALI/ARDS patients at intensive care units, comments Faron's CEO **Markku Jalkanen**. We are very satisfied with our collaboration with Rentschler and their experience with manufacturing and formulation of interferon-beta. This agreement allows Faron to move to final clinical development stage of Traumakine®, and to file marketing authorization application to European Medicines Agency (EMA) following the conduction of the pan-European pivotal trial in years 2012-14, continues Jalkanen.
- Rentschler has the longest history of IFN-beta manufacturing and formulation development in the world, and is therefore the best partner for Faron's Traumakine® project, comments **Klaus Schoepe**, Senior Vice President Client Relations of Rentschler. We bring to this product our process of IFN-beta manufacturing together with our capacity to finalize the Faron product and are very motivated to aid Faron in bringing Traumakine® to global markets in this new indication ALI/ARDS, continues Schoepe.

About ALI/ARDS 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 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. 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.

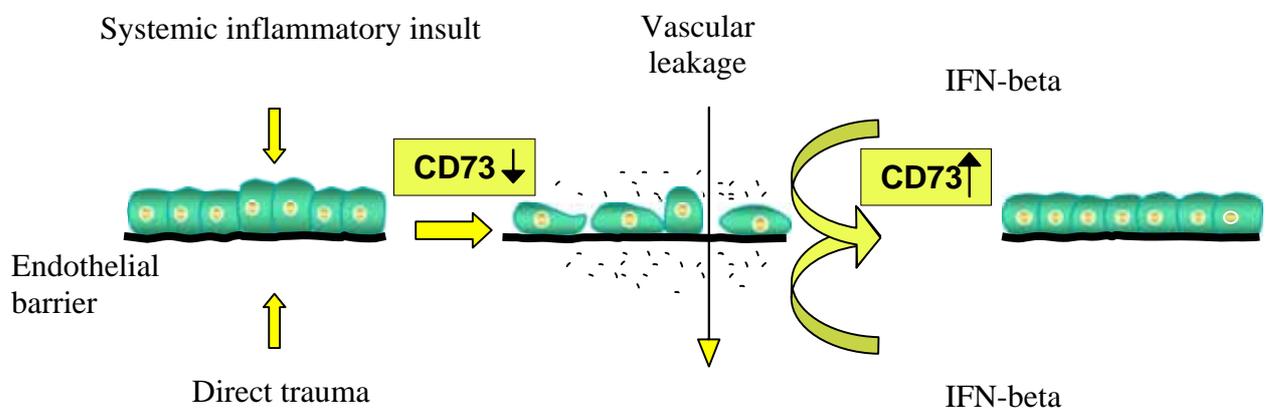


Figure 1: A model of IFN-beta action in acute injuries and prevention of vascular leakage

Faron has been granted an orphan drug status for interferon beta (FP-1201) in ALI/ARDS by European Commission and European Medicines Agency (EMA) under the registration number EU/3/07/505. Faron has also been granted several patents both in USA and Europe for this new use of IFN's to treat various ischemic conditions.

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 Traumakine® is currently being assessed in a phase I/II study in the UK to treat vascular leakage in ALI/ARDS patients. For more information, visit www.faronpharmaceuticals.com



About Rentschler Biotechnologie – www.rentschler.de

Rentschler Biotechnologie GmbH is a global full-service contract manufacturer with more than 30 years of experience in the development, production and approval of biopharmaceuticals in compliance with international GMP standards (EMA/FDA). Rentschler Biotechnologie has nine GMP suites with volumes of 30, 50, 250, 500, 1,000 and 2,500 liters, allowing the production of material for clinical trials (phase I to III) and for market supply. Rentschler also provides regulatory advice, protein analytics, quality control, and the sterile filling of syringes and injection vials. The company is family-owned and independent and has currently about 600 employees.

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