Press release

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Promising new treatment for life threatening acute respiratory distress syndrome (ARDS)

Turku – Finland, January 2, 2013. Together with its network of scientists and clinicians Faron Pharmaceuticals Ltd. has developed a promising new treatment for life threatening acute respiratory distress syndrome (ARDS). The FPCLI001 study, which reduced the odds of all cause mortality by more than 80 percent among the ARDS patients, has been published online in the distinguished medical journal: *The Lancet Respiratory Medicine.*

Acute respiratory distress syndrome (ARDS) is the major cause of death in intensive care units. It is estimated that approximately 300 – 400 thousand people suffer from ARDS each year in Western countries and the mortality rate remains high, around 35-45%, despite modern day care. At the moment there is no effective pharmacotherapy for the syndrome, hence treatment comprises of mechanical ventilation and optimization and support of vital functions.

"We are very pleased to have the FPCLI001 trial results and some related information published in this prestigious journal", stated Faron's CEO **Markku Jalkanen**. "We hope that this publication promotes our effort to attract active intensive care sites and clinicians to join our next step, the pan-European phase III pivotal trial with FP-1201-lyo starting in 2014," adds Jalkanen.

Significant reduction in all cause mortality following FP-1201 treatment

The published research article incorporates both molecular studies of Professor **Sirpa Jalkanen** (University of Turku, Finland) and a clinical study set up sponsored by Faron Pharmaceuticals. The clinical study (phase I/II) was conducted in 8 intensive care units around the UK and led by Dr **Geoff Bellingan** MD PhD from the University College London Hospitals. The clinical study demonstrated a significant reduction in mortality in ARDS patients. All other measured parameters, e.g. length of mechanical ventilation needed, length of ICU stay and support of vital functions also clearly benefitted from the treatment.

"Pulmonary vascular leakage occurs early in ARDS, and mortality remains high. An effective pharmacotherapy is desperately needed. The active pharmaceutical ingredient of FP-1201, interferon-beta has been shown to reduce capillary leak and thus we were very happy to see this translate into a benefit in ARDS patients as we predicted. We were particularly gratified to see such a significant reduction in mortality following the FP-1201 treatment", says

Dr. **Bellingan** and finishes: "We are eagerly looking forward to start further clinical investigations with this exciting drug candidate".

Faron has been granted an orphan drug status for the treatment of ALI/ARDS with interferon-beta by the European Commission and European Medicines Agency (EMA) and is waiting for EMA advise to start phase III studies.

ARDS is a significant financial burden to hospitals and societies

In addition to its high rate of mortality ARDS is also a major economic burden to hospitals and health care budgets. It is estimated that due to a long ICU and hospital stay the cost of every saved live from ARDS is approximately $70 000 USD. With a new efficient pharmacotherapy these costs will most likely diminish significantly. More capacity can be unleashed from intensive care, which may become highly needed, especially in major catastrophes and pandemic situations.

Major causes of ARDS include direct lung injury such as lung infection (pneumonia), aspiration pneumonia or indirect injuries such as severe sepsis, major multiple trauma or pancreatitis. The incidence of ARDS was seen to increase significantly in recent influenza pandemics.

Referred publication

Bellingan G, Maksimow M, Howell D, Stotz M, Beale R, Beatty M, Walsh T, Binning A, Davidson A, Kuper M, Shah S, Cooper J, Waris M, Yegutkin G, Jalkanen J, Salmi M, Piippo I, Jalkanen M, Montgomery H, Jalkanen S (2014) The effect of intravenous interferon-beta-1a (FP-1201) on lung CD73 expression and on acute respiratory distress syndrome mortality: an open-label study. *The Lancet Respiratory Medicine* on-line #S2213-2600(13)70259-5.

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