Interferon-beta treatment of acute respiratory distress syndrome (ARDS)

From 2012-12-01 to 2018-05-31, closed project

Objective

This application aims at a European marketing application for an orphan indication of the biopharmaceutical interferon-beta (IFN-beta) (EU3/07/505), to treat acute lung injury (ALI) and acute respiratory distress syndrome (ARDS). Despite the much improved mechanical ventilation techniques and improved supportive therapies, ARDS kills 35-40% of the 175,000 annual European patients. This condition has no approved pharmacological treatment in Europe. The applicant, Faron Pharmaceuticals, has recently finished a clinical phase I/II study with ALI/ARDS patients to obtain initial safety and pharmacokinetics for IFN-beta. Moreover, the study demonstrated very significant drop in all cause mortality of the IFN-beta treated patients at the day 28, the only accepted efficacy measurement as the primary end point for the treatment of ALI/ARDS. The pharmacological effect of IFN-beta is based on its ability to increase the de novo synthesis of endothelial cell surface anti-inflammatory molecule CD73, which can locally produce the enzymatic end product adenosine. Adenosine, in turn, increases endothelial barrier function and prevents the key step of ALI/ARDS process – vascular leakage. Faron and its clinical network will conduct a pan-European pivotal phase III study for further safety and pharmacokinetics of IFN-beta. If phase II reduction in all cause mortality of the IFN-beta treated ARDS patients can be replicated in a bigger study, the data would allow a marketing application for European regulatory authorities but also a much improved understanding what clinical parameters and biomarkers can attribute to the outcome of this deadly process in lungs. We also anticipate to harmonize European ARDS treatment and to create ARDS specific analytics for future ARDS diagnosis and treatment efficacy. ARDS patients represent massive cost burden to hospitals, societies and insurance companies. New medication for ALI/ARDS is much hoped and most welcome by intensive care doctors.

Related information

Report Summaries

Final Report Summary - TRAUMAKINE (Interferon-beta treatment of acute respiratory distress syndrome (ARDS))
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