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Abionyx Pharma announces success in fighting sepsis-triggered AKI

Abionyx Pharma SA has announced positive data from Phase IIa testing of iCER-001, a recombinant apoA-I, as a treatment for septic patients at high risk of developing Acute Kidney Injury (AKI)

After AM-Pharma's human recombinant alkaline phosphatase, ilofotase alfa, missed the endpoint of improving overall survival in patients with sepsis-induced acute kidney injury in October 2022, there is a complete lack of treatment options for septic patients at high risk of developing AKI, which caused estimated 13.7 million deaths globally. Now a new candidate treatment is at the horizon.

According to a Phase IIa pilot study enrolling 20 patients with bacterially induced sepsis at high risk for developping AKI, Abionyx Pharma SA's recombinant apoA-I iCER-001 was able to scavenge endotoxins, to modulate the cytokine storm, and to prevent endothelial disruption. The latter was only achieved up to now by Adrecizumab, an antibody drug developed by German Adrenomed AG, that has just entered a pivotal Phase III clinical trial.

In Abionyx's RACERS study that enrolled patients with a decline in function of one or more organ systems, three dosage regimens of CER-001 (five patients per group). The main objective of this pilot study was to find a therpeutic window for CER-001 and to investigate its potential to mitigate endotoxin-caused inflammatory response and prevent the progression to AKI according to KDIGO (Kidney Disease: Improving Global Outcomes) criteria.

According to the results of the pilot study, CER-001 led to a rapid and sustained reduction in endotoxin levels, reduction in the inflammatory cascade relative to SOC alone while at the same time normalising the apoA-I level in patients. Endothelial surrogate markers suggest a significant protective effect of CER-001.

In contrast to Adrenomed, which uses Adrenomedullin as stratification biomarker and adrecizumab as a therapeutic, the French company uses apoA-I, both as a biomarker and therapy.

After a safe dose level has now been established, Abionyx Pharma is going to validate its findings in a larger patient population.