

Abionyx bullish on acute kidney injury drug's prospects

French biotech Abionyx Pharma (Euronext: ABNX) has reported that the pilot Phase IIa trial of CER-001 as a treatment for septic patients at high risk of developing acute kidney injury (AKI) met its primary objective.

Secondary endpoints were also met in the RACERS study, the goal of which was to investigate whether the use of CER-001 at different doses, in combination with standard of care treatment, is safe and effective, and to establish safety and tolerability of the dosage regimens in order to select the optimal dose.

"The broad pleiotropic effect of our apoA-I bioproduct can target multiple facets of septic disease" Loreto Gesualdo, head of the Nephrology, Dialysis and Transplantation Unit, University of Bari Aldo Moro, Italy, and lead investigator of the RACERS study, said: "There is a complete lack of treatment options for septic patients at high risk of developing AKI, a disease that in 2019 had an estimated 13.7 million related deaths globally.

"The trial shows promising positive results across a variety of primary and secondary endpoints. CER-001 was significantly able to scavenge endotoxins, modulate the cytokine storm, and provide endothelial protection. The trend observed in reducing renal damage, the need for organ support and intensive care unit-day stay underscores the potential clinical significance of these results."

Connie Peyrottes, senior vice president for clinical development at Abionyx, said: "In this pilot study, CER-001 was shown to directly decrease endotoxin and inhibit inflammation, limiting the associated downward spiral that septic patients often experience. The broad pleiotropic effect of our apoA-I bioproduct can target multiple facets of septic disease, rather than focusing on a single step in the inflammatory process.

"Primary and secondary endpoints showed benefits of CER-001 therapy when added to standard treatments. The positive results from this Phase IIa trial show CER-001 has the potential to be a game-changer for critical illnesses marked by inflammation and organ failure across different high mortality clinical indications which continue to have high unmet medical needs."

The potential use of CER-001 in septic patients is currently under clinical development. These data will be discussed with regulatory authorities, starting with Europe but also the USA later this year, in order to design an appropriate clinical and regulatory development strategy.