Abionyx Pharma's Phase IIa trial of CER-001 for AKI meets primary objective

CER001 showed sustained endotoxin level reduction and consequent decline in the inflammatory cascade in the trial.

Abionyx Pharma has reported that its Phase IIa pilot clinical trial of CER-001 to treat septic patients who are at increased risk of developing acute kidney injury (AKI) met its primary goal.

The RACERS trial of CER-001, a natural recombinant apoA-I, included 20 gram-negative sepsis patients at high acute kidney injury risk due to increased endotoxin activity levels and a decline in function of one or more organ systems.

Subjects in the trial were given either standard of care (SOC) treatment alone, or along with one of three CER-001 dosage regimens.

The trial was aimed at studying whether the use of CER-001 at varying doses and SOC treatment is safe and effective.

Abionyx Pharma clinical development senior vice-president Connie Peyrottes 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.

"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 gamechanger for critical illnesses marked by inflammation and organ failure across different high mortality clinical indications which continue to have high unmet medical needs."

For the first time in a human pilot trial, the RACERS study demonstrated that the recovery of a normal apoA-I level in patients stops the cytokine storm while improving clinical outcomes.

In this trial, CER001 showed sustained endotoxin level reduction and a consequent decline in the inflammatory cascade or 'cytokine storm' relative to SOC alone.

Safety and efficacy, observed in RACERS, were said to be consistent with historical data, including clinical results for CER-001 in Covid-19 that were published in September last year.

The open-labelled, randomised, placebo-controlled, parallel-group trial was designed to assess the safety and efficacy of intravenously administered CER-001 in sepsis patients.

It randomised a total of 20 patients to receive eight CER-001 doses for six days on top of SOC, or SOC alone.

AKI's onset and severity according to the Kidney Disease: Improving Global Outcomes (KDIGO) criteria was the study's primary endpoint.

Safety and tolerability of the dosage regimens to select the optimal CER-001 dose was also included as the primary endpoint.