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Evaluation of efficacy, safety and treatment patterns of sodium zirconium cyclosilicate in management of hyperkalemia in China: an interim analysis (Actualize)

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Objectives : Sodium zirconium cyclosilicate (SZC), a novel highly selective potassium binder is approved in China for the treatment of hyperkalemia (HK), a potential life-threatening electrolyte imbalance condition. This interim analysis from an ongoing multi-center, prospective, non-interventional study evaluated the efficacy, safety and treatment patterns of SZC in Chinese HK patients under real-world setting (NCT 05271266).

Methods : This study included patients ≥ 18 years with documented HK from 40 sites in China, taking/willing to take SZC treatment. The interim analysis included patients who have completed 1 month follow-up. As per Chinese label, SZC treatment was categorized into correction phase (FAS-P1) and maintenance phase (FAS-P2); the treatment was discontinued as per HK threshold (5.3/5.5 mmol/L in most sites under real-world setting). The study evaluated changes in serum K⁺ (sK⁺) levels and incidence of adverse events (AEs).

Results : A total of 193 patients and 354 patients were enrolled in FAS-P1 and FAS-P2, respectively. With an SZC mean daily dose of 11.5g in FAS-P1, the sK⁺ levels reduced significantly from baseline, 5.9 mmol/L to 5.0 mmol/L (Δ sK⁺ -0.9 mmol/L), after correction phase, 51.3% and 77.8% patients showed sK⁺ levels between 3.5-5.0 mmol/L and 3.5-5.5 mmol/L. With a SZC median daily dose of 5g in FAS-P2, the mean sK⁺ levels were 5.1 mmol/L during the maintenance treatment. SZC was well tolerated with only 1.5% and 0.5% patients in FAS-P1 and FAS-P2, respectively reporting AEs with no severe AEs and treatment discontinuations.

Conclusions : From the interim analysis, SZC was effective and safe in treating HK. Hence, SZC can be considered a standard treatment for acute and chronic HK in China.