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P252 -REAL-WORLD EXPERIENCE OF THE SAFETY AND EFFECTIVENESS OF SUCROFERRIC OXYHYDROXIDE IN UK DIALYSIS PATIENTS: AN INTERIM SUBGROUP ANALYSIS OF THE VERIFIE STUDY

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INTRODUCTION: Sucroferric oxyhydroxide is a non-calcium-, iron-based phosphate binder (PB) indicated for the treatment of hyperphosphatemia in patients on dialysis. The VERIFIE (Velphoro Evaluation of Real-lIfe saFety, effectIveness and adherencE) study is evaluating the safety and effectiveness of sucroferric oxyhydroxide prescribed to dialysis patients in routine clinical practice.

METHODS: VERIFIE is a non-interventional, prospective, multicentre, European cohort study (scheduled observation period per patient: 12–36 months; planned enrolment: 1000 patients). This interim analysis, performed 24 months after first patient, first visit, reports safety and effectiveness outcomes for the subgroup of UK patients enrolled in the study. Two patient groups were analysed: the 'safety analysis set' (patients who received ≥1 dose of sucroferric oxyhydroxide and had safety data available) and the 'full analysis set' (patients who received ≥1 dose of sucroferric oxyhydroxide and had effectiveness data available).

RESULTS: In total, 48 patients enrolled at UK study sites were included in the safety analysis set (mean age 52.2 years; 75.0% male). Of those, 42 patients were included in the full analysis set for evaluation of the effectiveness of sucroferric oxyhydroxide, including changes in serum phosphorus levels. The mean observation period was 112.7 days. Prior PB use was reported for 30 patients (62.5%) at study entry, including lanthanum (30.0% of patients), sevelamer (26.7%) and calcium-based PBs (26.7%). The mean daily dose of sucroferric oxyhydroxide remained unchanged during the observation period, ranging from 1135.4 mg (2.3 pills/day) at baseline (BL) to 1130.2 mg (2.3 pills/day) at the time of last documented dose. In total, 13 (27.1%) patients received concomitant PB therapy (in addition to sucroferric oxyhydroxide) during the observation period. In total, 24 patients (50.0%) reported ≥1 adverse drug reaction, most of which were gastrointestinal-related, mainly diarrhoea and discoloured faeces (Table). Eleven patients (22.9%) withdrew from the study prematurely during the observation period. Mean serum ferritin level at BL was 360.7 ng/mL and small increases were observed at Month 3 (+69.5 ng/mL; p=0.028) and Month 6 (+134.4 ng/mL; not significant). No significant changes in transferrin saturation or haemoglobin levels were observed. Treatment with sucroferric oxyhydroxide was associated with reductions in mean serum phosphate from BL to Month 3 (–0.14 mmol/L; not significant) and Month 6 (–0.36 mmol/L; p=0.024). The proportion of patients with serum phosphorus levels ≤1.78 mmol/L increased from 25.0% at BL to 35.7% at Month 3, and

to 37.5% at Month 6. There were no significant changes in serum calcium or intact parathyroid hormone levels during the observation period.

DISCUSSION: Sucroferric oxyhydroxide was well tolerated by UK dialysis patients, and no new safety risks were identified in this real-world study. Sucroferric oxyhydroxide was effective for the reduction of serum phosphorus levels. These findings for the UK patient subgroup were generally comparable with those observed for the overall study population.