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ILLUMINATE-C, a Single-Arm, Phase 3 Study of Lumasiran in Patients with Primary Hyperoxaluria Type 1 and CKD3b-5, Including Those on Hemodialysis

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We present the 6-month primary analysis data from ILLUMINATE-C, a single-arm, phase 3 study to evaluate lumasiran, an RNAi therapeutic which inhibits oxalate production, in patients with PH1 and impaired kidney function.

Key inclusion criteria: genetically confirmed PH1 diagnosis, eGFR ≤45 mL/min/1.73 m2, plasma oxalate (POx) ≥20 µmol/L (upper limit of normal=12 µmol/L). Cohort A: patients who did not require dialysis or kidney transplantation at study start. Cohort B: patients on hemodialysis. Primary endpoints: percent change in POx from baseline to Month (M) 6 (cohort A); percent change in pre-dialysis POx from baseline to M6 (cohort B).

Baseline mean (SD) POx was 64.7 (41.3) µmol/L in cohort A (N=6) and 108.4 (29.5) µmol/L in cohort B (N=15). In cohorts A and B, respectively, lumasiran led to 33.33% (95%CI: −15.16, 81.82) and 42.43% (95%CI: 34.15, 50.71) least-square mean reductions in POx from baseline to M6 (averaged across M3–6). The most common lumasiran-related AEs were injection-site reactions (all mild).

Lumasiran resulted in substantial reductions in POx in PH1 patients with CKD 3b–5, with an acceptable safety profile through M6.

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