CONVERTING FROM DOXERCALCIFEROL INJECTION TO DOXERCALCIFEROL CAPSULES IN CKD PATIENTS ON HD: A RANDOMIZED, OPEN-LABEL STUDY TO DETERMINE CLINICALLY APPROPRIATE DOSES

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Background: Doxercalciferol is available as capsules for PO administration and as a liquid for IV administration. This study was performed to evaluate the transition from IV to PO dosing with doxercalciferol.

Methods: This was a randomized, open-label study. Following a 5-week, doxercalciferol injection (DI) Run-in period, 42 HD patients were randomly assigned to 1 of 3 groups, stratified by DI Run-in dose: 1) doxercalciferol capsules (DC) dose = 1.0 x DI dose, 2) DC dose =1.5 x DI dose, or 3) DC dose = 2.0 x DI dose. Patients were treated at the assigned dose for 5 weeks. The difference in iPTH values between the average of the last 3 measurements collected during the last week of the DI Run-in period and the average of the last 3 measurements collected during the last week of the DC treatment period was the primary efficacy endpoint.

Results: The mean difference in iPTH levels between the average of the DC treatment period and the DI Run-in period was 4.88 pmol/L in the 1.0 conversion group, 0.41 pmol/L in the 1.5 conversion group and -5.88 pmol/L in 2.0 conversion group. A conversion factor of 1.49 of the DC dose relative to the DI dose provides equivalent iPTH control. Calcium and phosphorus levels remained stable at all conversion factors.

Conclusion: Using a conversion factor of 1.5 hemodialysis patients treated with doxercalciferol injection can be safely switched to doxercalciferol capsules and maintain comparable inhibition of PTH.