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

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Paricalcitol (Zemplar®) is an active synthetic vitamin D_2 analogue. Doxercalciferol (Hectorol®) is a vitamin D_2 prodrug that is converted by the liver to active 1,25-dihydroxycalciferol. Both paricalcitol and doxercalciferol are available as capsules for PO administration and as a liquid for IV injection. A conversion factor of approximately 60% has been found in previous studies to be appropriate when converting from IV paricalcitol to IV doxercalciferol, but the transition from IV paricalcitol to PO doxercalciferol has not been evaluated in a clinical study. This study was performed to provide dosing information for conversion from IV paricalcitol to PO dosing with doxercalciferol.

This was a randomized, open-label study. Following a 5-week, paricalcitol injection (PI) Run-in period, 39 HD patients were randomly assigned to 1 of 3 groups, stratified by PI Run-in dose: 1) doxercalciferol capsules (DC) dose = 0.5 x PI dose, 2) DC dose =1.0 x PI dose, or 3) DC dose = 1.5 x PI 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 PI 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. The study is complete but the results were not available at the time of the abstract submission. The results will be presented at the 2008 NKF Meeting.