



Fresenius Medical Care

P R E S S E - I N F O R M A T I O N

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Fresenius Medical Care Announces FDA Submission of New Drug Application for PhosLo

Bad Homburg, Germany – Fresenius Medical Care today announced the submission of a supplemental New Drug Application (sNDA) with the U.S. Food & Drug Administration (FDA) to allow the Company's proprietary phosphate binder, PhosLo to be labeled for use by patients diagnosed with Stage 4 chronic kidney disease (CKD). The U.S. National Kidney Foundation divides kidney disease into five stages depending on the glomerular filtration rate (GFR) which ranges from more than 90 ml/min in healthy kidneys (Stage 1) to less than 15 ml/min (Stage 5) where dialysis or a kidney transplant is needed. Persons with CKD Stage 4 have advanced kidney damage with a severe decrease in the GFR to 15-29 ml/min, i.e. the filtration rate is significantly lower compared to average healthy kidneys. It is likely someone with Stage 4 CKD will need dialysis or a kidney transplant in the near future. There are approximately 400,000 patients with Stage 4 CKD in the U.S.

The submission of the sNDA is based on data from the "Effect of Calcium Acetate on Phosphorus Levels in Patients with Advanced Chronic Kidney Disease" (EPIC) study. The study, which was presented at the International Society of Nephrology meeting in Copenhagen, Denmark, October 13, 2006, was a prospective, multi-center, randomized, double-blind, placebo-controlled study designed to evaluate the efficacy and safety of PhosLo in 110 Stage 4 CKD pa-

tients. The study achieved its primary endpoint of superior control of serum phosphorus levels ($p=0.0003$), the calcium-phosphorus product ($p=0.001$) and serum parathyroid hormone (PTH) ($p=0.001$) versus placebo.

Dr. Ben Lipps, Chief Executive Officer of Fresenius Medical Care, commented: “We are pleased with the outcome of the EPIC study, which has resulted in the FDA submission. When the application is granted, PhosLo will provide nephrologists another therapeutic option that will allow them to start treatment of hyperphosphatemia earlier.”

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PhosLo is a registered trademark of Fresenius Medical Care.

About Hyperphosphatemia

Hyperphosphatemia is an electrolyte disturbance in which there is an abnormally elevated level of phosphate in the blood. Often, calcium levels are lowered (hypocalcemia) due to precipitation of phosphate with the calcium in tissues. It is associated with secondary hyperparathyroidism and commonly seen in chronic renal failure. High phosphate levels can be avoided with phosphate binders and dietary restriction of phosphate.

About PhosLo

PhosLo is an oral prescription calcium acetate phosphate binder currently indicated for the control of elevated phosphorous levels in patients with end stage renal disease (ESRD). PhosLo is administered orally, and when given with food, it combines with dietary phosphate to form insoluble calcium phosphate complexes that are eliminated from the body, thereby reducing phosphorus absorption, helping to prevent excess blood phosphorus levels. Patients should have serum calcium levels closely monitored and their dose of PhosLo adjusted or terminated to bring levels to normal. PhosLo is contraindicated in patients with hypercalcemia. No other calcium supplements should be given concurrently with PhosLo. PhosLo is well tolerated and has an excellent safety profile. Nausea, hypercalcemia, and pruritus (itching) have occasionally been reported during PhosLo therapy.

Fresenius Medical Care is the world's largest integrated provider of products and services for individuals undergoing dialysis because of chronic kidney failure, a condition that affects more than 1,400,000 individuals worldwide. Through its network of 2,085 dialysis clinics in North America, Europe, Latin America, Asia-Pacific and Africa, Fresenius Medical Care provides dialysis treatment to 161,433 patients around the globe. Fresenius Medical Care is also the world's leading provider of dialysis products such as hemodialysis machines, dialyzers and related disposable products. Fresenius Medical Care is listed on the Frankfurt Stock Exchange (FME, FME3) and the New York Stock Exchange (FMS, FMS-p).

For more information about Fresenius Medical Care visit the Company's website at www.fmc-ag.com.

This release contains forward-looking statements that are subject to various risks and uncertainties. Actual results could differ materially from those described in these forward-looking statements due to certain factors, including changes in business, economic and competitive conditions, regulatory reforms, foreign exchange rate fluctuations, uncertainties in litigation or investigative proceedings, and the availability of financing. These and other risks and uncertainties are detailed in Fresenius Medical Care AG & Co. KGaA's reports filed with the U.S. Securities and Exchange Commission. Fresenius Medical Care AG & Co. KGaA does not undertake any responsibility to update the forward-looking statements in this release.