



Fresenius Medical Care

## P R E S S   R E L E A S E

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### **Fresenius Medical Care Announces Continued Positive Data from CARE-2 Database**

**Bad Homburg, Germany** – During the American Society of Nephrology's Renal Week 2007 additional findings from the Calcium Acetate Renagel Evaluation (CARE 2) data set were presented by Dr. Wajeh Qunibi of the University of Texas Health Science Center, San Antonio. The study showed that there are no significant differences in aortic or mitral valve calcification between hemodialysis patients treated with PhosLo and those treated with selevamer if LDL is kept at constant levels. Previous findings from the same study have already shown that there is no difference in overall cardiovascular calcification in both treatment groups. The new findings also showed that the daily calcium intake from the use of calcium acetate as a phosphate binder for one year did not contribute to the progression of cardiovascular calcification in hemodialysis patients. These conclusions are consistent with the initial CARE-2 data presented at ASN renal week 2006.

PhosLo's safety and efficacy was further validated by the results of the Dialysis Clinical Outcomes Revisited (DCOR) trial, the first interventional outcomes study published in *Kidney International*, November 2007. The DCOR trial clearly demonstrated that there were no statistically significant differences in the all-cause or cardiovascular mortality among 2,100 hemodialysis patients randomized to

sevelamer or calcium-based phosphate binders (CBPB). Additionally, a review of the laboratory data in DCOR demonstrated that the CBPB group had significantly better serum phosphorus and intact parathyroid hormone compared to the sevelamer group ( $p < 0.01$ ).

These findings will provide additional data on the safety of PhosLo as the Company works with the Food and Drug Administration (FDA) to expand the PhosLo label indication to chronic kidney disease (CKD) pre-dialysis. On October 16, 2007, the FDA's Cardiovascular and Renal Drugs Advisory Committee's recommended that the FDA extend the use of phosphate binders in pre-dialysis patients with hyperphosphatemia. This favorable vote will allow the Company to work with the FDA on the regulatory pathway to this important label extension.

Dr. Ben Lipps, Chairman of the Management Board and Chief Executive Officer commented, "This data continues to validate our goal of providing safe and effective treatments to patients with bone and mineral abnormalities by offering pharmaceutical treatments as a part of our integrated "pharma-tech" therapy."

### **About CARE-2**

The CARE-2 study was a prospective, randomized, controlled head-to-head comparison between PhosLo and sevelamer with the addition of atorvastatin calcium, as appropriate, in both treatment groups to control LDL (low density lipoprotein) levels. The study found not statistically significant difference in the progression of cardiovascular calcification (CAC) between the two treatment groups after 12 months of treatment. Patients treated with PhosLo and sevelamer achieved comparable reductions in serum phosphorus and calcium-phosphorus product and even more importantly K/DOQI target levels were reached significantly faster with PhosLo.

### **About PhosLo**

PhosLo is a calcium acetate phosphate binder for oral application in renal disease patients. Excess phosphate consumed with food is normally removed by the kidneys in a process that can only partially be replaced by dialysis in patients with chronic kidney failure. Too much phosphate in the blood can result in a number of adverse

events, including bone disease, thyroid problems and vascular calcification. The risk of such damage in end-stage renal disease patients can be lowered by regularly taking phosphate binders. Currently, the phosphate binder market exceeds \$500 million worldwide. PhosLo is a trademark of Fresenius Medical Care.

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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 1,500,000 individuals worldwide. Through its network of 2,221 dialysis clinics in North America, Europe, Latin America, Asia-Pacific and Africa, Fresenius Medical Care provides dialysis treatment to 172,227 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](http://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.