



Fresenius Medical Care

P R E S S – R E L E A S E

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Fresenius Medical Care announces encouraging results of CALMAG study on phosphate binder OsvaRen[®] at the 2010 EDTA congress in Munich

Bad Homburg, Germany – Based on data from its recently completed CALMAG (CALcium acetate MAGnesium carbonate evaluation) study, Fresenius Medical Care is announcing a demonstration of the effectiveness of its combined phosphate binder OsvaRen[®] (calcium acetate/magnesium carbonate) in the treatment of hyperphosphatemia in hemodialysis patients. A scientific symposium unveiling these findings will take place during the 2010 European Dialysis and Transplant Association (EDTA) congress in Munich, Germany (June 25-28).

The CALMAG study is a 24-week, head-to-head, prospective, controlled, randomized, multicenter, clinical study comparing the efficacy of two phosphate binders, OsvaRen[®] and Renagel[®] (sevelamer hydrochloride, Genzyme Corp.) in 255 patients with chronic kidney disease on hemodialysis in five European countries. Over the long term, OsvaRen[®] reduced serum phosphorus to lower levels than sevelamer hydrochloride and kept serum calcium at comparable levels. In patients receiving OsvaRen[®], the risk of hypercalcemia did not increase. OsvaRen[®] was well-accepted and well-tolerated by hemodialysis patients. Publication of the results has been accepted by *Nephrology Dialysis Transplantation* and already is available online: <http://ndt.oxfordjournals.org/papbyrecent.dtl>.

“The CALMAG study underlines our commitment to the best treatment for dialysis patients. These results bring us one step closer to our vision of truly integrated care,” said Dr. Emanuele Gatti, Fresenius Medical Care’s chief executive officer for Europe, Latin America, the Middle East and Africa and global chief strategist.

At the symposium titled “Magnesium – beneficial effects over & above phosphate binding,” study data will be presented by Professor Adrian Covic from Iași, Romania – a clinical investigator and member of the European Renal Association-European Dialysis and Transplant Association (ERA-EDTA) Scientific Committee. The symposium will take place on June 26 from 1:00 until 2:30 p.m. on the first floor of the International Congress Centre Munich (ICM), Room 14 A.

Background information:

About the CALMAG study

The CALcium acetate MAGnesium carbonate evaluation (CALMAG) study¹ is a 24-week randomized, controlled, parallel-group, multicenter study. It enrolled 255 adult patients with chronic kidney disease undergoing dialysis in five European countries (Germany, Poland, Portugal, Romania and Spain). The patients were randomly assigned to treatment with OsvaRen[®] or sevelamer hydrochloride (Renagel[®], Genzyme Corp.).

Observed mean serum phosphorus levels were well within the target range during OsvaRen[®] treatment [in accordance with target ranges recommended by international KDOQI (Kidney Disease Outcomes Quality Initiative) guidelines]. OsvaRen[®] achieved faster and better serum phosphorus control in a larger number of patients compared to sevelamer hydrochloride. The rise in total serum calcium in the OsvaRen[®] group was not clinically relevant, nor was there any difference in ionized serum calcium and episodes of hypercalcemia between both groups.

There were no significant differences in the number of patients with any adverse events during treatment. However, fewer patients in the OsvaRen[®] group experienced any drug-related adverse events or any adverse event leading to study withdrawal during the CALMAG study. A lower pill burden was shown for the OsvaRen[®] treatment versus sevelamer hydrochloride.

About OsvaRen®

OsvaRen®, consisting of 435 mg calcium acetate (equivalent to 110 mg calcium) and 235 mg magnesium carbonate (equivalent to 60 mg magnesium) enables effective and well-tolerated control of serum phosphorus levels in patients on dialysis. Elevated serum phosphorus levels are an independent predictor of mortality in patients with chronic renal failure and requiring effective treatment for better achievement of K/DOQI (Kidney Disease Outcomes Quality Initiative, Clinical Practice Guidelines for Bone Metabolism and Disease in Chronic Kidney Disease)² and KDIGO (Kidney Disease: Improving Global Outcomes)³ target ranges. In addition, OsvaRen® can be a more cost-effective option in the treatment of hyperphosphatemia compared to sevelamer hydrochloride. Meanwhile, OsvaRen® has been approved in 28 European countries for the treatment of hyperphosphatemia associated with chronic renal insufficiency in patients undergoing dialysis. OsvaRen® is not yet available in all countries, and prescribing information may differ between countries. Please consult your local prescribing information. For more information about OsvaRen®, please visit our website at www.fmc-renalpharma.com.

Important safety information

OsvaRen® is contraindicated in patients with hypophosphatemia, hypercalcemia with or without clinical symptoms, e.g., as a result of an overdose of vitamin D, a paraneoplastic syndrome (bronchial carcinoma, breast cancer, renal cell carcinoma, plasmacytoma), bone metastases, sarcoidosis or immobilization osteoporosis; elevated serum magnesium levels of more than 2 mmol/l, and/or symptoms of hypermagnesemia; AV-block III°; myasthenia gravis; hypersensitivity to the active substances or to any of the excipients.

Common adverse events reported with OsvaRen® include soft stools, gastrointestinal irritation such as nausea, anorexia, sensation of fullness, belching and constipation, diarrhea. Uncommon: moderate to severe symptomatic hypercalcemia, symptomatic hypermagnesemia. Very rare: hyperkalemia, magnesium-induced osteal mineralization disturbances.

Drug-drug interactions may occur with some medications and should be taken into consideration when instructing patients on how to take OsvaRen[®]. Patients should be informed to take OsvaRen[®] with meals and to adhere to their prescribed diets.

References:

¹ de Francisco ALM et al. Evaluation of calcium acetate/magnesium carbonate as a phosphate binder compared with sevelamer hydrochloride in hemodialysis patients: a controlled, randomized study (CALMAG study) assessing efficacy and tolerability. *Nephrol Dial Transplant* 2010; DOI 10.1093/ndt/gfq292.

² K/DOQI clinical practice guidelines for bone metabolism and disease in chronic kidney disease. *Am J Kidney Dis* (2003) 42, p.1-p.201.

³ KDIGO Guideline for Chronic Kidney Disease – Mineral and Bone Disorder. *Kidney International* (2009) 76 (Suppl 113), p.1-p.130.

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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 1,890,000 individuals worldwide. Through its network of 2,580 dialysis clinics in North America, Europe, Latin America, Asia-Pacific and Africa, Fresenius Medical Care provides dialysis treatment to 198,774 patients around the globe. Fresenius Medical Care also is 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.