

# PRESS RELEASE

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# Fresenius Medical Care announces presentation of first results from the CALMAG study for phosphate binder OsvaRen®

Fresenius Medical Care, the world's largest provider of dialysis products and services, today announces the presentation of the first results from the CALcium acetate MAGnesium carbonate evaluation study (CALMAG study) for the new phosphate binder OsvaRen<sup>®</sup> at the Renal Week 2009 in San Diego, USA.<sup>1</sup> The CALMAG study examines efficacy and safety of OsvaRen<sup>®</sup>.

The poster will be presented:

• 29<sup>th</sup> of October 2009, 10 am – 12 midday

Poster board: TH-PO615

 Lead investigator: Prof. Angel Luis Martín de Francisco, Universidad de Cantabria, Santander (Spain).

"Investment in the CALMAG study underlines our commitment to the best treatment for dialysis patients", said Dr. Emanuele Gatti, Chief Executive Officer of Fresenius Medical Care for the regions Europe, Latin America, Middle East and Africa. "These results bring us one step closer to our vision of truly integrated care."

## **Background information:**

# **About the CALMAG study**

The CALMAG study is a 24-week randomised, controlled, multicentre, head-to-head clinical study comparing the efficacy of two phosphate binders, OsvaRen<sup>®</sup> (calcium acetate/magnesium carbonate from Fresenius Medical Care) and sevelamer hydrochloride (Renagel<sup>®</sup> from Genzyme Corporation) in patients with chronic kidney disease on dialysis. The CALMAG study was conducted in five European countries.

#### About OsvaRen®

OsvaRen<sup>®</sup>, consisting of 435 mg calcium acetate (110 mg calcium) and 235 mg magnesium carbonate (60 mg magnesium), allows effective and safe 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 require effective treatment for better achievement of K/DOQl<sup>2</sup> and KDIGO<sup>3</sup> target ranges. OsvaRen<sup>®</sup> is now approved in 28 European countries for the treatment of hyperphosphataemia associated with chronic renal insufficiency in patients undergoing dialysis. OsvaRen<sup>®</sup> 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<sup>®</sup>, please visit our website <a href="https://www.fmc-renalpharma.com">www.fmc-renalpharma.com</a>.

## Important safety information

OsvaRen<sup>®</sup> is contraindicated in patients with hypophosphataemia, hypercalcaemia, elevated serum magnesium levels of more than 2 mmol/L and/or symptoms of hypermagnesaemia, AV-block III or Myasthenia gravis. Common adverse events reported with OsvaRen<sup>®</sup> include soft stools, gastrointestinal irritation like nausea, anorexia, sensation of fullness, belching and constipation, diarrhoea. Drug-drug interactions may occur with some medications and should be taken into consideration when instructing patients on how to take OsvaRen<sup>®</sup>. Patients should be informed to take OsvaRen<sup>®</sup> with meals and to adhere to their prescribed diets.

#### References:

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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 1,770,000 individuals worldwide. Through its network of 2,471 dialysis clinics in North America, Europe, Latin America, Asia-Pacific and Africa, Fresenius Medical Care provides dialysis treatment to 190,081 patients around the globe. Fresenius Medical Care is also the world's leading provider of dialysis products such as haemodialysis 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 <a href="www.fmc-ag.com">www.fmc-ag.com</a>.

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.

<sup>&</sup>lt;sup>1</sup> de Francisco ALM et al. A controlled randomised comparison of calcium acetate / magnesium carbonate (OsvaRen<sup>®</sup>) to sevelamer hydrochloride (Renagel<sup>®</sup>) in hemodialysis patients: the CALMAG study (2009). J Am Soc Nephrol 20: TH-PO615

<sup>&</sup>lt;sup>2</sup> K/DOQI clinical practice guidelines for bone metabolism and disease in chronic kidney disease. Am J Kidney Dis (2003) 42, p1-p201.

<sup>&</sup>lt;sup>3</sup> KDIGO Guideline for Chronic Kidney Disease -Mineral and Bone Disorder. Kidney International (2009) 76 (Suppl 113), p1–p130.