

MEDIA RELEASE

Date 29 June 2010
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Subject Vifor Pharma releases further positive study results and expands the collaboration with Fresenius Medical Care

((for public release on 29 June 2010 from 7.30 a.m. CET))

Vifor Pharma releases further positive study results and expands the collaboration with Fresenius Medical Care:

- **Promising Phase II study results with pipeline product PA21 - Phase III study to start soon in collaboration with FMC in the USA**
- **Ferinject[®] study in Gastroenterology met primary and secondary endpoints**
- **Independent study supports use of Venofer[®] in haemodialysis patients**
- **Positive ALMS results presented**

Four new studies provide further clinical evidence that therapies from Vifor Pharma, the Pharma business sector of the Galenica Group, have a major benefit for patients suffering from chronic diseases.

The Phase II study of the pipeline product PA21, a novel iron-based phosphate binder, met its primary endpoint: doses of PA21 between 5.0g/day to 12.5g/day were effective in reducing elevated serum phosphate in a dose dependent manner. Based on these data, Fresenius Medical Care will collaborate with Galenica/Vifor Pharma in the Phase III clinical study in the USA and will become the commercial partner for North America after the successful completion of this study.

The FERGI-COR (FERinject in GI disorders (IBD) to CORrect iron deficiency) study successfully demonstrated the efficacy as well as the favourable safety and tolerability profile of Ferinject[®] for correction of iron deficiency anaemia in patients with inflammatory bowel disease. The FERGI-COR study also met its primary and secondary endpoints.

An independent, observational study presented at the European Renal Association – European Dialysis and Transplant Association (ERA-EDTA) Congress in Munich, highlighted the negative clinical consequences that resulted from attempting to switch stable haemodialysis (HD) patients from Venofer[®] to a copy product (Iron Sucrose Similar - ISS). The study suggests that the copy product FerMylan[®] may not be therapeutically equivalent to Venofer[®]. A switch to the copy product resulted in the need for higher iron doses to reach and maintain target haemoglobin levels leading to an increase in overall medication cost.

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The results of these three studies represent an important step forward in the implementation of Vifor Pharma's growth strategy. Lastly, the maintenance phase of the 5 year Aspreva Lupus Management Study (ALMS) successfully demonstrated the superiority of CellCept® in the maintenance of remission in critically ill Lupus Nephritis patients and was presented at the 9th International Congress on Systemic Lupus Erythematosus in Vancouver.

Vifor Pharma achieved further important milestones in the implementation of its growth strategy, whose key elements are the development of its product pipeline, the increase of scientific evidence for the use of Ferinject® and information on the potential consequences of switching stable HD patients to alternative products. To achieve this strategy the company is investing significant resources, particularly in its clinical study program. Two Vifor Pharma and an independent observational study demonstrated positive results. Together these studies establish further medical evidence for the efficacy and favourable safety and tolerability profile of three Vifor Pharma products: the intravenous iron replacement preparations Ferinject® and Venofer® and the phosphate binder PA21, a pipeline product.

PA21, a novel iron based phosphate binder, met its primary and secondary endpoints in Phase II study

PA21 is a novel iron-based phosphate binder currently in clinical development. The Phase II dose finding and active-controlled study was conducted in approximately 150 patients on maintenance haemodialysis. The study met its primary and secondary endpoints: The results showed that doses of PA21 between 5.0g/day to 12.5g/day were effective in reducing elevated serum phosphate in a dose dependent manner. The serum phosphate lowering efficacy of the two lowest active doses of PA21 were comparable to Renagel® (sevelamer hydrochloride) 4.8g/day. PA21 was well-tolerated with an overall safety and tolerability profile comparable to Renagel®. The results of this study were presented on 26 June at the ERA-EDTA 2010 Congress. Data from this study were also presented to the FDA and two European National Regulatory Authorities in end of phase II meetings. Outcomes of these meetings were successful with clear guidance for a timely phase III clinical program. Based on these positive clinical results, Fresenius Medical Care will collaborate with Galenica/Vifor Pharma in the Phase III clinical study in the USA and will become the commercial partner for North America after the successful completion of this study. Both companies will review extending this collaboration to other territories.

Ferinject® corrects iron deficiency effectively with a simplified dosing scheme

FERGI-COR was a large, multi-centre, randomised, prospective, comparative, open-label, Phase III study. It investigated the efficacy, tolerability and safety of a simplified, standardised dosing scheme of Ferinject® for the correction of iron deficiency anaemia in patients with inflammatory bowel disease (IBD). The study was designed to determine whether a simplified and convenient dosing scheme of Ferinject® is at least as effective and well-tolerated as calculating individual doses of an established intravenous iron preparation by a complex formula. In this study both primary and secondary endpoints were met. The results show that the administration of Ferinject® increases haemoglobin levels by at least 2 g/dL which is similar or better than the comparator. The effectiveness of Ferinject® in replenishing iron stores and correcting anaemia with a simplified administration schedule will facilitate adherence to treatment and lessens the risk of dose miscalculation. Furthermore, a reduction in the number of infusions can make Ferinject® a more cost-effective and more convenient treatment in pa-

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tients with IBD associated iron deficiency compared to other intravenous iron products. Detailed results of the FERGI-COR study were submitted for presentation at a major medical congress in Gastroenterology taking place in late 2010.

Venofer® and Iron Sucrose Similar may not be therapeutically equivalent

Clinical data from an independent, observational study in haemodialysis (HD) patients, conducted by Dr Jacques Rottembourg, nephrologist at the Centre Suzanne Lévy, Paris, showed that Venofer® and the iron sucrose similar FerMylan® may not be therapeutically equivalent. HD patients with anaemia and iron deficiency were treated for almost six years with erythropoiesis-stimulating agents (ESA) and Venofer® with satisfactory clinical results. The switch to FerMylan® led to a loss of haemoglobin control of the patients who were destabilized causing a decrease in Hb levels and iron indices. A direct consequence of the switch was that previously well-controlled patients required higher drug doses (about 35% more iv iron and about 12% more ESA) to re-establish and maintain target Hb levels with a resultant increase in anaemia medication costs by 12%.

The switch resulted in chronically ill HD patients being exposed to higher doses of ESA and i.v. iron, in order to achieve the same therapeutic effect.

Results of the study were also presented at the ERA-EDTA 2010 Congress, on 27 June.

CellCept® superior to azathioprine in the prevention of relapse of Lupus Nephritis - Clinical data presented at 9th International Congress on Systemic Lupus Erythematosus in Vancouver

Clinical data from the ALMS maintenance study were presented by Dr David Wofsy MD, rheumatologist, Veterans Affairs Medical Center, San Francisco at the 9th International Congress on Systemic Lupus Erythematosus. In this 3 year maintenance phase of the study, subjects with active Lupus Nephritis who had responded to induction therapy were assigned to receive either azathioprine (AZA) 2mg/kg/day or CellCept® 2g/day for up to 3 years.

Of the 227 patients entering the maintenance phase, more CellCept®-treated patients completed the full 3 years of therapy than those on AZA (CellCept® 62.9% vs AZA 48.6%)

CellCept® was significantly superior to AZA with respect to:

- Primary endpoint of time to treatment failure ($p=0.003$) defined as either death, end stage renal disease, doubling of serum creatinine, lupus nephritis flare or requirement for rescue therapy with high dose corticosteroids.
- Key secondary endpoint of time to broader definition of treatment failure (death, end stage renal disease, doubling of serum creatinine, lupus nephritis flare, major extra-renal flare or rescue therapy for any lupus flare, or withdrawals for any reason) ($p=0.032$).

Both drugs were well tolerated however there were more clinically significant serious adverse events in the AZA group compared to the CellCept® treated patients. These results lead to the conclusion that CellCept® demonstrated improved clinical benefit over azathioprine in this difficult to treat disease.

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***Galenica** is a diversified group active throughout the healthcare market which, among other things, develops, manufactures and markets pharmaceutical products, runs pharmacies, provides logistical and database services and sets up networks. The Galenica Group enjoys a leading position in all of its business sectors – Pharma, Logistics and Retail. A large part of the Group's income is generated by international operations.*

Additional information on the Galenica Group can be found at www.galenica.com.

***Vifor Pharma**, the Pharma business sector of the Galenica Group, researches, develops, manufactures and markets pharmaceutical products, with focus on the treatment of iron deficiency, where Vifor Pharma is one of the leading companies. It also conducts clinical studies for the application of medications for the treatment of various autoimmune diseases. Furthermore, Vifor Pharma manufactures prescription and over-the-counter (OTC) products developed within the company or produced or sold under license, and markets them on international markets. Vifor Pharma is headquartered in Switzerland (Zurich).*

Additional information about Vifor Pharma can be found at www.viforpharma.com

About Ferinject®

Ferinject® is an innovative intravenous iron replacement product discovered and developed by Vifor Pharma. Ferric carboxymaltose, the active pharmaceutical ingredient of Ferinject®, overcomes the unmet clinical needs of i.v. iron therapy as Ferinject® is not associated with dextran-induced hypersensitivity reactions and has a low potential for iron toxicity. Ferinject®, in doses up to 1000 mg iron, can be administered in a 15 minute drip infusion in patients with iron deficiency associated with a variety of clinical conditions.

So far, Ferinject® gained marketing authorisation in 23 European countries and Switzerland as well as in South Korea for the treatment of iron deficiency where oral iron is ineffective or cannot be used. In many countries, intravenous iron replacement products are primarily used to treat dialysis patients. However, iron deficiency is also part of many other illnesses representing a great market potential for Vifor Pharma's iron product. Ongoing development of scientific evidence supporting the use of Ferinject® outside of dialysis therefore has top priority. Vifor Pharma is evaluating new opportunities in the treatment of iron deficiency with Ferinject® in different therapeutic areas. Trials with Ferinject® in chronic kidney disease (CKD), oncology (anaemia in cancer patients), gastroenterology (inflammatory bowel diseases), and gynaecology are ongoing or planned.

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About Venofer[®]

Venofer[®] (iron sucrose) is an intravenous iron replacement therapy for the treatment of iron deficiency especially used in haemodialysis. Built on more than 50 years of experience, Venofer[®] has a favourable safety profile and it is targeted and efficient. It is registered in 86 countries and since 1994 over 240 mio units have been sold.

About CellCept[®]

CellCept[®] (mycophenolate mofetil) is given to people who have received kidney, heart or liver transplants in order to prevent rejection, a process where the immune system perceives the new organ as a "foreign" threat and attacks it.

CellCept[®], an immunosuppressant medication, is taken along with other antirejection drugs. Patients must follow their doctor's exact instructions for taking CellCept[®] and all other medications.

The use of CellCept[®] along with other medications that help prevent transplanted organs from being rejected may result in an increased chance of getting infections and the possible development of lymphomas and other cancers, especially skin cancer. Patients must contact their doctor right away if they notice any signs of infection (such as fever, tiredness, headache, redness of skin/wound or enlarged glands).

Women of childbearing potential must use birth control. Use of CellCept[®] during pregnancy is associated with increased risk of miscarriage and congenital malformations (birth defects).

The most common side effects of CellCept[®] include: diarrhea, leukopenia (a decrease in white blood cells), sepsis (an infection in the blood), vomiting and a higher incidence of certain infections. People taking CellCept[®] in combination with other medications that help prevent transplanted organs from being rejected have a greater chance of developing lymphomas and other cancers, especially skin cancer.

Women of childbearing age must use 2 highly effective methods of birth control 4 weeks prior to starting CellCept[®] therapy and continue birth control until 6 weeks after stopping CellCept[®] treatment, unless abstinence is the chosen method. Patients considering pregnancy must talk to their doctor, as CellCept[®] should not be used unless they cannot be successfully treated with other immunosuppressant drugs.

Cases of progressive multifocal leukoencephalopathy (PML), an infection of the brain that is sometimes fatal, have been reported in patients treated with CellCept[®]. In reported cases, patients generally had risk factors for PML, including treatment with therapies that suppress the immune system. The most common symptoms may include: clumsiness, progressive weakness, loss of movement or function in one side of the body, and changes in vision, speech or personality.

Severe neutropenia (a decrease in neutrophils, a type of white blood cell) has been reported in up to 2% of kidney, 2.8% of heart and 3.6% of liver transplant patients receiving CellCept[®] at a dose of 3 grams daily.

Gastrointestinal bleeding (requiring hospitalization) has been reported in approximately 3% of kidney, 1.7% of heart and 5.4% of liver transplant patients treated with CellCept[®] at a dose of 3 grams daily. For the full prescribing information for CellCept[®], including Boxed WARNINGS and Medication Guide, please visit www.cellcept.com.