

MEDIA RELEASE

Date 3 June 2010
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Subject CellCept[®] reaches positive results in Phase III trial in Lupus Nephritis

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Vifor Pharma, the pharma business sector of the Galenica Group, and Roche (SIX: RO, ROG; OTCQX: RHHBY), today announced that the maintenance phase of the Aspreva Lupus Management Study (ALMS) has successfully achieved its primary endpoint. The trial demonstrates the superiority of Roche's CellCept[®] (mycophenolate mofetil) versus azathioprine (AZA) in delaying treatment failure in patients with Lupus Nephritis (LN). ALMS is one of the largest studies ever conducted in LN.

ALMS Maintenance was designed to establish the efficacy of CellCept[®] compared to AZA as maintenance therapy in LN patients who had successfully responded to induction treatment (ALMS Induction, reported June 2007) with either CellCept[®] or intravenous cyclophosphamide (IVC). Topline primary endpoint results for the trial indicate that CellCept[®] was superior to AZA in delaying the time to treatment failure (p=0.003). The safety profiles of both drugs were consistent with those previously reported with no new safety signals observed. Vifor Pharma plans to present these results at the 9th International Congress on Systemic Lupus Erythematosus (SLE) to be held in Vancouver, Canada from 24-27 of June 2010. Additional analyses are ongoing.

Dr Ellen Ginzler, Chief of Rheumatology and Professor of Medicine, SUNY Downstate Medical Center New York, USA and lead investigator for the study in the US, said: "Despite recent advances in the treatment of Lupus, the disease may still relapse after successful treatment and is very difficult to study. These ALMS Study results are promising for patients who need treatment options as it has been more than 50 years since a new treatment for Lupus has been approved by the FDA."

In light of these positive topline results, and assuming the final results are consistent, Vifor Pharma and Roche are assessing the potential to seek regulatory approval in the U.S., Europe and other major markets for the use of CellCept[®] in the treatment of LN.

About the study

In total, 227 patients participated in ALMS Maintenance, with 116 receiving CellCept[®] and 111 receiving AZA. The primary efficacy parameter was time to treatment failure, comprising death, serious renal damage or relapse of LN. Patients were treated for up to 3 years.

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About Lupus Nephritis

Systemic lupus erythematosus (SLE), commonly called lupus, is a chronic autoimmune disease that causes the body to attack its own tissues and joints. The majority of subjects with SLE are women (80-90%) with an onset in children or young adults. It is estimated that 1 per 1,000 women of child-bearing age are affected. It is also estimated that 30-50% of patients with SLE will develop nephritis that requires medical intervention and treatment. Nephritis caused by SLE is termed Lupus Nephritis (LN).

Lupus nephritis, considered life-threatening, but rare, is the most serious manifestation of SLE. If left untreated, it can lead to kidney failure, need for dialysis, and potentially death. It is a complicated disease as patients typically fluctuate between periods of intense disease activity, during which the patient's own immune system is actively attacking and causing damage in their kidneys, and periods of remission. Vifor Pharma estimates that there are about 600,000 diagnosed lupus nephritis patients worldwide.

There have been no new approved treatment options for SLE or lupus nephritis in the United States in over fifty years. Current practice for the treatment on LN divides drug therapy into induction treatment for the control of active and potentially life threatening disease, and maintenance treatment for the prevention of relapse. Current treatment is largely based on systemic immunosuppression using corticosteroids in combination with other second-line drugs such as CellCept[®], cyclophosphamide or azathioprine. These immunomodulating therapies have proven beneficial as steroid-sparing agents; however, there are few, if any, controlled studies for many of these therapies.

About CellCept[®]

CellCept[®] (mycophenolate mofetil) is an immunosuppressant approved for use in combination with other immunosuppressive drugs (cyclosporine and corticosteroids) for the prevention of rejection in patients receiving kidney, heart and liver transplants.

There are no adequate and well-controlled studies in pregnant women. As CellCept[®] has been shown to have teratogenic effects in animals at subclinical doses on a body surface area basis, it may cause fetal harm when administered to a pregnant woman. CellCept[®] should not be used in pregnant women unless the potential benefit justifies the potential risk to the fetus. Women of childbearing potential should have a negative serum or urine pregnancy test with a sensitivity of at least 50 mIU/mL within one week prior to beginning therapy even where there has been a history of infertility, unless due to hysterectomy.

Women of childbearing potential must use effective contraception before beginning CellCept[®] therapy, during therapy and for six weeks following discontinuation of therapy. Two reliable forms of contraception must be used simultaneously unless abstinence is the chosen method. If pregnancy occurs during treatment, the physician and patient should discuss the desirability of continuing the pregnancy (see complete product information).

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Adverse events reported in >30% of renal, cardiac or liver transplant patients receiving CellCept[®] (in combination with cyclosporine and corticosteroids) were pain, fever, headache, asthenia, anemia, leucopenia (patients should be monitored for neutropenia; dosing should be interrupted or the dose reduced if neutropenia develops), thrombocytopenia, leukocytosis, urinary tract infection, hypertension, hypotension, peripheral edema, hypercholesteremia, hypokalemia, hyperglycemia, creatinine, BUN and cough increased, hypomagnesemia, diarrhea, constipation, nausea, vomiting, respiratory infection, dyspnea, lung disorder, pleural effusion, tremor and insomnia.

Patients receiving immunosuppressant regimens are at increased risk of developing lymphomas and other malignancies, particularly of the skin.

CellCept[®] has not been approved by the FDA for the treatment of any autoimmune disease, including Lupus Nephritis.

Warning: Increased susceptibility to infection and the possible development of lymphoma may result from immunosuppression. Only physicians experienced in immunosuppressive therapy and management of renal, cardiac or hepatic transplant patients should use CellCept[®]. Patients receiving the drug should be managed in facilities equipped and staffed with adequate laboratory and supportive medical resources.

For further information:

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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.

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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).

In 2007 Galenica acquired the Aspreva Pharmaceuticals Corporation. The integration of Aspreva was the start of a fully integrated specialty pharma group called Vifor Pharma within the Galenica Group's Pharma business sector. Since July 2003, former Aspreva has had an innovative indication development partnership with Roche in place whereby the company investigates CellCept[®]'s clinical utility within autoimmune diseases. The ALMS study was a 5 year study to investigate CellCept[®]'s utility in Lupus Nephritis.

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

Roche: Headquartered in Basel, Switzerland, Roche is a leader in research-focused healthcare with combined strengths in pharmaceuticals and diagnostics. Roche is the world's largest biotech company with truly differentiated medicines in oncology, virology, inflammation, metabolism and CNS. Roche is also the world leader in in-vitro diagnostics, tissue-based cancer diagnostics and a pioneer in diabetes management. Roche's personalised healthcare strategy aims at providing medicines and diagnostic tools that enable tangible improvements in the health, quality of life and survival of patients. In 2009, Roche had over 80'000 employees worldwide and invested almost 10 billion Swiss francs in R&D. The Group posted sales of 49.1 billion Swiss francs. Genentech, United States, is a wholly owned member of the Roche Group. Roche has a majority stake in Chugai Pharmaceutical, Japan.

Additional information about Roche can be found at www.roche.com

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