

NEWS RELEASE

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FDA APPROVES LONGER USE OF VALCYTE® FOR ADULT KIDNEY TRANSPLANT PATIENTS AT HIGH RISK OF DEVELOPING CYTOMEGALOVIRUS (CMV) DISEASE

-- CMV is the Most Important and Common Viral Infection Complicating Solid Organ Transplantation --

South San Francisco, Calif. -- August 10, 2010 -- Genentech, Inc., a member of the Roche Group (SIX: RO, ROG; OTCQX: RHHBY), announced today that the U.S. Food and Drug Administration (FDA) approved increasing the length of therapy with Valcyte (valganciclovir hydrochloride) in adult kidney transplant patients at high risk for cytomegalovirus (CMV) disease.

The supplemental approval is based on data that showed longer prophylactic treatment with Valcyte reduced the incidence of CMV disease in high-risk adult kidney transplant patients from 36.8 percent (for patients who received 100 days of treatment) to 16.8 percent (for patients who received treatment for 200 days) at one year after receiving a transplanted kidney ($p < 0.0001$).^{1,2} The overall safety profile of Valcyte did not change with the extension of prophylaxis in high-risk kidney transplant patients.

“Among the different risks people face after a kidney transplant, CMV is one that may be prevented through prophylactic treatment with Valcyte,” said Investigator, Dr.

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Atul Humar, Director, Transplant Infectious Diseases and Associate Professor, Department of Medicine, University of Alberta, Canada. “Data now demonstrate that we may further reduce the risk of CMV infection by increasing the duration of preventative treatment from 100 to 200 days.”

CMV is a major cause of illness and disease during the first six months following transplantation. It is estimated that 50-80 percent of all adults are infected with the CMV virus,¹ which most often lies dormant in the body throughout life. The virus can be activated at times when the immune system is weakened such as after organ transplantation. CMV infection may cause complications in the lungs, kidneys, nervous system, liver, and gastrointestinal tract.²

“Despite advances in the management of CMV, studies have shown that more than a third of patients still develop CMV infection even after 100 days of prophylaxis,” said Hal Barron, M.D., executive vice president, Global Development and chief medical officer. “This approval provides important information for physicians treating high-risk adult patients during the critical period after kidney transplant.”

About Pivotal Clinical Study

The IMPACT study for the prevention of CMV disease in adult kidney allograft (transplant) recipients was a global, multi-center (65 centers in 13 countries including the United States), double-blind study that randomized 326 high-risk (donor CMV

seropositive/recipient CMV seronegative) kidney allograft recipients to one of two treatment groups:

- 100 days Valcyte (900 mg once daily) post-transplant followed by 100 days placebo
- 200 days Valcyte (900 mg once daily) post-transplant

The primary endpoint of the study was the proportion of patients who developed protocol-defined CMV disease within the first 52 weeks (12 months) post-transplant. Secondary endpoints included safety, time to CMV disease, time to CMV infection, acute rejection, and graft loss. Definitions of CMV disease were consistent with the American Society of Transplantation (AST) guidelines for use in clinical trials.

The most common adverse events occurring in the Valcyte-treated patients (200 day and 100 day groups) were low white blood cell counts (26 percent vs. 38 percent), diarrhea (26 percent vs. 31 percent), and swelling in the extremities (peripheral edema) (21 percent vs. 19 percent).³ The most serious adverse events in the Valcyte-treated patients were hypertension (12 percent vs. 13 percent), transplant rejection (6 percent vs. 9 percent), and tremors (17 percent vs. 12 percent). Four deaths, unrelated to treatment with Valcyte, occurred in the 100-day treatment group. These were attributed to hemorrhage (one), sepsis (one) or septic shock (two).⁴

The percentage of kidney transplant patients with CMV disease at 24 months post-transplant was 38.7 percent (63/163) for the 100 day dosing regimen and 21.3 percent (33/155) for the 200 day dosing regimen (p=0.0008).

Treatment duration for high-risk adult heart and kidney-pancreas transplant patients is still 100 days, as per the Valcyte Prescribing Information.

About CMV

CMV belongs to the family of herpes viruses and, as such, is very common among the general population.⁵ CMV is the most common and single most important viral infection complicating solid organ transplantation. Transplant patients may already be infected with CMV prior to transplantation or receive a donor organ infected with CMV.

About Valcyte

Valcyte is an antiviral medicine. In adults, it is used to treat CMV retinitis in people who have acquired immunodeficiency syndrome (AIDS). When CMV virus infects the eyes, it is called CMV retinitis. Valcyte is used to prevent CMV disease in people who have received a heart, kidney, or kidney-pancreas transplant and who have a high risk of getting CMV disease.

In children (4 months to 16 years of age) Valcyte tablets or oral solution are used to prevent CMV disease in children who have received a heart or kidney transplant and have a high risk for getting CMV disease. Valcyte is not approved for use in adults or children who have received a liver transplant.

It is not known if Valcyte is safe and effective to prevent CMV disease in people who have had other types of organ transplant such as lung or intestine, or to prevent CMV disease in children under 4 months of age who receive an organ transplant, or to treat CMV disease that a baby might be born with (congenital CMV disease), or in adults older than age 65.

Valcyte Safety

Valcyte can affect blood cells and bone marrow causing serious and life-threatening problems. Valcyte can lower the amount of white blood cells, red blood

cells, and platelets. Patients' doctors may do regular blood tests to check blood cells while patients are taking Valcyte. Based on these tests, the doctor may change the dose or tell patients to stop taking Valcyte.

Valcyte may cause cancer. Valcyte causes cancer in animals. It is not known if Valcyte causes cancer in people.

Valcyte may cause birth defects. Valcyte causes birth defects in animals. It is not known if Valcyte causes birth defects in people. Patients who are pregnant must speak with their doctor before taking Valcyte. Patients must tell their doctor right away if they become pregnant while taking Valcyte. If female patients can become pregnant, they should use effective birth control during treatment with Valcyte and for at least 30 days after treatment. Men should use a condom during treatment with Valcyte, and for at least 90 days after treatment, if their female sexual partner can become pregnant. Patients should talk to their doctor if they have questions about birth control. Valcyte may lower the amount of sperm in a man's body and cause fertility problems.

Valcyte can affect the kidney, including serious problems such as kidney failure. A patient's doctor may do regular blood tests to check kidney function while a patient is taking Valcyte. The doctor may adjust the dose based on these tests.

Valcyte changes into the medicine ganciclovir once it is in the body. Ganciclovir is also the active ingredient in Cytovene-IV and ganciclovir capsules.

Patients must not take ganciclovir capsules or Cytovene-IV if they are taking Valcyte.

The dose of medicine in Valcyte tablets and ganciclovir capsules is different. One tablet of Valcyte has more medicine than one capsule of ganciclovir. This means that one Valcyte tablet cannot be substituted for one ganciclovir capsule.

Patients could overdose and become very sick if Valcyte is taken with ganciclovir capsules or Cytovene-IV. Patients should talk to their doctor or pharmacist if they have questions about their medicine.

Valcyte does not cure CMV retinitis. People may still get retinitis or worsening of retinitis during or after treatment with Valcyte. It is important they stay under a doctor's care and have their eyes checked regularly. The safety and efficacy of Valcyte have not been established in patients younger than 4 months of age. The safety and efficacy of Valcyte have not been studied in adults older than age 65.

Patients must not take Valcyte tablets if they are receiving hemodialysis. The use of ganciclovir rather than Valcyte tablets is recommended.

Patients must not take Valcyte if they are allergic to any of its ingredients or if they have ever had a serious reaction to ganciclovir capsules or Cytovene-IV. Symptoms of an allergic reaction to Valcyte may include: sudden trouble breathing, wheezing, hives all over the body, swelling around the mouth, or feeling anxious.

Before taking Valcyte, patients should tell their doctor if they:

- have kidney problems. The doctor may give them a lower dose of Valcyte, or check them more often if they are taking Valcyte.

- have blood cell problems
- are having radiation treatment
- have any other medical conditions
- are pregnant or plan to become pregnant. It is not known if Valcyte causes birth defects in an unborn baby. **Patients must tell their doctor right away if they become pregnant while taking Valcyte.**
- are breast-feeding or plan to breast-feed. It is not known if Valcyte passes into milk and if it may harm the baby. Patients should not breast-feed if they are HIV-positive because of the chance of passing the HIV virus to the baby through their milk.

Patients should tell their doctor about all the medications they take, including prescription and non-prescription medicines, vitamins, and herbal supplements. Valcyte and other medicines may affect each other and cause serious side effects. Patients should tell their doctor if they take didanosine (Videx[®]), zidovudine (Retrovir[®], Trizivir, Combivir), probenecid (Col-Probenecid, Probenacid and Colchicine), mycophenolate mofetil (CellCept[®]).

Common side effects of Valcyte in adults and children include diarrhea, nausea, vomiting, fever, and shaky movements (tremors), low white cell, red cell and platelet counts in blood tests, and rejection of the transplanted organ (graft).

Other common side effects in children include constipation, high blood pressure, cough and colds.

Patients should tell your doctor if they have any side effect that bothers them or that does not go away.

For the full prescribing information for Valcyte, including Boxed WARNINGS, please visit <http://www.valcyte.com>.

About Genentech

Founded more than 30 years ago, Genentech is a leading biotechnology company that discovers, develops, manufactures and commercializes medicines to treat patients with serious or life-threatening medical conditions. The company, a member of the Roche Group, has headquarters in South San Francisco, California. For additional information about the company, please visit <http://www.gene.com>.

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¹ Centers for Disease Control and Prevention. CMV Overview.

² Medscape. Infection in the Transplant Recipient: CMV.

³ Humar A et al. The Efficacy and Safety of 200 Days Valganciclovir Cytomegalovirus Prophylaxis in High-Risk Kidney Transplant Recipients. *Am J Transplantation* 2010; 10:1228.

⁴ Humar A et al. The Efficacy and Safety of 200 Days Valganciclovir Cytomegalovirus Prophylaxis in High-Risk Kidney Transplant Recipients. *Am J Transplantation* 2010; 10:1228.

⁵ Centers for Disease Control and Prevention. CMV Overview.