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FDA Approves Valcyte® (valganciclovir hydrochloride) to Prevent Cytomegalovirus (CMV) Disease in Pediatric Patients Who Receive Heart or Kidney Transplants

-- Plus new oral solution offers dosing flexibility for pediatric patients --

Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today that the U.S. Food and Drug Administration (FDA) has approved Valcyte® (valganciclovir hydrochloride) for the prevention of cytomegalovirus (CMV) disease in pediatric kidney and heart transplant patients (4 months to 16 years of age) at high risk of developing CMV disease. The FDA also approved a new pediatric oral solution formulation for Valcyte, which will allow easier administration to pediatric patients 4 months to 16 years of age.

“Children receiving organ transplants are especially vulnerable to infection because of their reduced immunity, and the invasive procedure of a transplant can put them at higher risk of contracting CMV infection,” noted Richard Freeman, M.D., Vice Chair for Research, Department of Surgery, Professor of Surgery, Tufts Medical Center. “Prevention and medication dosing can be challenging because children are not small adults. The new oral formulation and information about how to administer the medicine will help doctors treat their pediatric transplant patients.”

CMV (herpesvirus) infects approximately 80 percent of the U.S. population depending on age. In the majority of cases the virus lies dormant in the body throughout life, but can be reactivated at times when the immune system is weakened (such as transplant patients and AIDS patients). In patients who have received an organ transplant, CMV infection usually develops during the first few months after transplantation, and may cause complications in the lungs, kidneys, nervous system, liver, and gastrointestinal tract. CMV can lead to the loss of the transplanted organ, and studies have shown that the virus has been correlated with an increased risk of death in post-transplant patients.

Over the past 21 years, more than 35,000 children ages 17 and younger have been transplant recipients in the U.S. Before preventative measures were taken to reduce the risk of infection, CMV among pediatric transplant patients was found in 26 percent of thoracic organ and 22 percent of kidney recipients.

New Pediatric Indication in Organ Transplant Patients

Valcyte, the leading anti-CMV agent, is now approved for the prevention of CMV disease in pediatric patients 4 months to 16 years of age who have

undergone kidney or heart transplantation and who are at high risk for developing CMV disease. The safety and efficacy of Valcyte has not been established in the prevention of CMV disease in pediatric solid organ transplant patients under 4 months of age or for the treatment of congenital CMV.

About Valcyte

Valcyte tablets are indicated for the treatment of CMV retinitis in patients with acquired immunodeficiency syndrome (AIDS). Valcyte is indicated for the prevention of CMV disease in kidney, heart, and kidney-pancreas transplant patients at high risk. Valcyte is not indicated for use in liver transplant patients. The safety and efficacy of Valcyte for the prevention of CMV disease in other solid organ transplant patients such as lung transplant patients have not been established.

The clinical toxicity of Valcyte, which is metabolized to ganciclovir, includes granulocytopenia, anemia, and thrombocytopenia. In animal studies, ganciclovir was carcinogenic, teratogenic, and caused aspermatogenesis.

Valcyte tablets should not be administered if the absolute neutrophil count is less than 500 cells/micro liter, the platelet count is less than 25,000/micro liter, or the hemoglobin is less than 8 g/dL. Severe leukopenia, neutropenia, anemia, thrombocytopenia, pancytopenia, bone marrow depression, and aplastic anemia have been observed in patients treated with Valcyte tablets (and ganciclovir). Other adverse events reported with frequency of > or = to 5 percent included diarrhea, tremors, graft rejection, nausea, headache, insomnia, hypertension, vomiting, and fever.

In adult liver transplant patients, there was a significantly higher incidence of tissue-invasive CMV disease in the Valcyte-treated group compared with oral ganciclovir group. Valcyte is not for use in the prevention of CMV disease in children who have received a liver transplant.

Strict adherence to dosage recommendations is essential to avoid overdose. Dose modifications are required for patients with renal impairment.

Prescribing information for Valcyte is available at www.rocheusa.com/products/valcyte or www.rochetransplant.com.

About 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 personalized healthcare strategy aims at providing medicines and diagnostic tools that enable tangible improvements in the health, quality of life and survival of patients. In 2008, Roche had over 80,000 employees worldwide and invested almost 9 billion Swiss francs in R&D. The Group posted sales of 45.6 billion Swiss francs. Genentech, United States, is a wholly owned member of the Roche Group. Roche has a majority stake in Chugai Pharmaceutical, Japan. For more information: www.roche.com.

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