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CellCept registry data demonstrated superior long-term organ transplant outcomes
Data from more than 25,000 CellCept patients support strong track record in organ transplantation

Data presented yesterday at a top U.S. transplant meeting demonstrated better patient and graft (organ) survival in liver and kidney transplant patients taking CellCept (mycophenolate mofetil) compared to those receiving treatment regimens not including CellCept. These findings revealed a significant improvement in outcomes over previous standards of transplantation care and are part of a still-growing body of data on CellCept, which received FDA approval in 1995.

The data were presented at the American Transplant Congress and focused on the results of two separate studies. In total, the studies looked at nearly 35,000 organ recipients from the Scientific Registry of Transplant Recipients (SRTR), of which more than 25,000 received CellCept-based treatment regimens. The two studies covered six and fours years, respectively, of post-surgical outcomes.

"CellCept has had a significant effect on the improvement of organ transplant outcomes over the past nine years," said Herwig-Ulf Meier-Kriesche, M.D., associate professor, University of Florida College of Medicine and lead author of the renal transplantation study. "Data such as these are critical to increasing our understanding of the full scope of treatment options for transplant recipients. The more long-term information physicians have, the more the standard of care will continue to improve."

On average, 70 people receive transplants from either a living or deceased donor every day and over 25,500 transplants are performed each year. Currently, there are more than 84,000 people on the nation's organ transplant waiting list.

"Over the past decade, CellCept has helped to improve the lives of thousands of kidney, liver and heart transplant recipients," said Robert Gordon, M.D., medical director of organ transplantation at Roche. "The wealth of data and positive experiences using CellCept further supports its use in kidney, liver and heart transplantation and demonstrates significant improvement over past experience."

Examination of CellCept treatment in Liver transplantation
The study, Efficacy of Triple Therapy with Mycophenolate Mofetil (MMF), Tacrolimus (Tacro) and Corticosteroids (CS) Compared to Tacro and CS Immunosuppression in Liver Transplantation: An Analysis of the US Liver Transplant Experience, examined the hypothesis that triple therapy with MMF + Tacro + CS was associated with improved patient survival and graft survival. Investigators analyzed data from 11,670 adult primary liver transplant recipients 18 - 80 years old (7,204 Tacro + CS; 4,466 MMF + Tacro + CS) reported to the SRTR between January 1, 1995 and April 30, 2001.

Results showed improved efficacy and safety associated with the addition of MMF to a Tacro + CS immunosuppressive regimen as demonstrated by significant improvement in patient and graft survival, as well as reduced risk for infectious death, when compared to Tacro + CS therapy.

Univariate analyses showed the MMF + Tacro + CS group was associated with statistically significant improvement in patient survival (81.4% vs. 77.2%, p<0.0001), graft survival (77.7% vs. 74.2%, p<0.0001) and death-censored graft survival (87.0% vs. 83.9%, p=0.0002) at four years, compared to the Tacro + CS group.

Multivariate analyses showed the MMF + Tacro + CS group was associated with a reduced risk for graft loss (RR=0.84, p=0.001), death-censored graft loss (RR=0.81, p=0.001), and patient death (RR=0.80, p=0.001).

MMF + Tacro + CS group was associated with a reduced risk of death from infectious causes (RR=0.83, p=0.02). Infectious deaths from bacterial causes were lower in the MMF + Tacro + CS group than the Tacro + CS group (3.2% vs. 4.1%, p=0.01). There was no difference between the two groups for fungal (p=0.08) or viral infectious deaths (p=0.77).

Examination of CellCept treatment in renal transplantation
The study, Sirolimus (RAP) in Combination with Cyclosprine Microemulsion (CSA) vs. Mycophenolate Mofetil (MMF) with CSA is Associated with Decreased Graft Survival (GS) in Renal Transplant (Tx) Recipient, was designed to evaluate the association between RAP + CSA therapy vs. MMF + CSA and graft survival in adult primary renal Tx patients. The study used 2003 SRTR data and evaluated 21,017 MMF + CSA and 1,999 RAP + CSA patients who received kidney transplants since January 1, 1998.

This study found that RAP + CSA was associated with significantly worse graft survival compared to MMF + CSA. Specifically, in univariate analyses, RAP + CSA was associated with significantly lower 4-year graft survival (74.6% vs. 79.3%, p=0.0021) and death-centered graft survival (83.7% vs. 87.2%, p=0.0029) vs. MMF + CSA. In the multivariate analysis, RAP + CSA was associated with a significantly increased risk for graft loss and death-centered graft loss. Results with strategies of CSA sparing, or use of alternative agents, with RAP cannot be assumed or extrapolated from this data.

About the SRTR registry
The SRTR supports the ongoing evaluation of the scientific and clinical status of solid organ transplantation in the United States and analyzes transplantation trends and organ procurement organization (OPO) performance among major solid organ transplantation categories in the United States. It is administered by the University Renal Research and Education Association (URREA) in conjunction with the University of Michigan.

About CellCept
CellCept is an immunosuppressant or anti-rejection drug used in combination with other immunosuppressive drugs (cyclosporine and corticosteroids) for the prevention of rejection in patients receiving heart, kidney and liver transplants. CellCept received FDA approval for the prevention of organ rejection in kidney (May 1995), heart (February 1998), and liver (July 2000). The recommended dosages for CellCept follow: for adult kidney transplants, 2 g daily; for pediatric kidney transplants, oral suspension 600 mg/m2; for adult heart and liver, 3 g/day.

There are no adequate and well-controlled studies in pregnant women. As CellCept (mycophenolate mofetil) 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 6 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).

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, leukopenia*, 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.

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. The physician responsible for maintenance therapy should have complete information requisite for the follow-up of the patient. For full prescribing information, visit www.rocheusa.com/products/cellcept/pi.html.

About Roche
Headquartered in Basel, Switzerland, Roche is one of the world's leading innovation-driven healthcare groups. Its core businesses are pharmaceuticals and diagnostics. Roche is number one in the global diagnostics market, the leading supplier of pharmaceuticals for cancer and a leader in virology and transplantation. As a supplier of products and services for the prevention, diagnosis and treatment of disease, the Group contributes on a broad range of fronts to improving people's health and quality of life. Roche employs roughly 62,000 people in 150 countries. The Group has alliances and research and development agreements with numerous partners, including majority ownership interests in Genentech and Chugai.

*Patients should be monitored for neutropenia. Dosing should be interrupted or the dose reduced if neutropenia develops.

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