

Basel, 15 November 2000

### **Roche gains European approval for CellCept in Liver Transplant Patients to help fight rejection**

Roche announced today that the European Commission has approved the expanded use of its immunosuppressant drug, CellCept (mycophenolate mofetil), for the prevention of organ rejection in patients undergoing liver transplantation. There are nearly 4000 liver transplants performed in Europe each year.

CellCept is already approved around the world for the prevention of organ rejection in patients undergoing kidney and heart transplantation and was approved for the liver transplant indication in the US in August this year.

#### **CellCept effective anti-rejection tool in liver transplantation**

The European Union based its decision on a double-blind, randomised 565 patient multi-centre study which examined the effect of CellCept on acute rejection and survival in liver transplant patients comparing its use against azathioprine (AZA) both in combination with cyclosporine and corticosteroids. The study, led by Dr. Russ Wiesner of Mayo Clinic, Rochester, MN, showed CellCept to be superior to AZA in preventing acute rejection six months post-transplant. Rate of death or re-transplantation in comparison one year later was similar to AZA (14.7% vs 14.6% respectively).

Dr. Hari Kumar, Life Cycle Leader CellCept, Roche, said "This controlled multi-centre study, along with numerous single-centre studies, confirms that CellCept is a very effective anti-rejection tool in kidney, heart and now liver transplants. The licence is very good news for liver transplant patients as they can now receive CellCept which has been shown to be more effective than standard immunosuppressant therapy. Organ transplants are major operations and we want to give patients the best possible outcome."

Patients enrolled in the study received CellCept 1 g twice daily intravenously for up to 14 days followed by CellCept 1.5 g twice daily orally, or azathioprine 1-2 mg/kg/day intravenously followed by azathioprine 1-2 mg/kg/day orally in combination with cyclosporine and corticosteroids as maintenance immunosuppressive therapy.

#### **About CellCept**

CellCept, (mycophenolate mofetil, MMF) an immunosuppressant, is a potent and reversible inhibitor of a key enzyme, inosine monophosphate dehydrogenase, IMPDH. CellCept is registered in over 70 countries around the world for the prevention of organ rejection in patients undergoing kidney and heart transplantation. Approval for the liver transplantation indication has been received in the US and other country approvals are pending.

#### **Roche and transplantation**

Roche continues to make a strong commitment to improve the success rate of transplantation while enhancing the quality of life for the patient. Roche has developed three innovative therapies that improve graft and post-transplant health - with the two non-nephrotoxic immunosuppressants CellCept and Zenapax and, in addition, with Cymevene for the prevention of cytomegalovirus infection. In July 1998, Roche also announced the establishment of the "Roche Organ Transplant Research Foundation." Roche has pledged CHF 25 million to this new non-profit Foundation over the next 5 years.

Headquartered in Basel, Switzerland, Roche is one of the world's leading research-oriented healthcare groups in the fields of pharmaceuticals, diagnostics and vitamins. Roche's innovative products and services address needs for the prevention, diagnosis and treatment of disease, thus enhancing people's well-being and quality of life. Roche has approximately 62,000 employees and sells its products in over 170 countries. The Roche Group posted sales of 20.3 billion Swiss francs in the first nine months of 2000. In the first half of 2000 the company's net income amounted to 3 billion Swiss francs. It invested 1.9 billion Swiss francs in research and development.

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