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First Genetically Engineered Drug To Reduce Risk Of Kidney Rejection Receives FDA Marketing Clearance
Unique mechanism of action of Zenapax® (Daclizumab) improves success rate of kidney transplants without increasing side effects

Nutley, N.J., December 11, 1997 -- Hoffmann-La Roche Inc. announced today that it has received marketing clearance from the U.S. Food and Drug Administration (FDA) for Zenapax® (Daclizumab), the first humanized monoclonal antibody to be included in an immunosuppressive regimen for use in patients who undergo a kidney transplant. Zenapax, when added to other anti-rejection drugs, reduced the incidence of kidney rejection episodes from 47 to 27 percent in one trial and from 35 to 22 percent in a second trial, without increasing most side effects.

In one of 2 trials, patient survival was significantly better in kidney-transplant patients one year after surgery. In those patients who received Zenapax with two other immunosuppressive drugs, significantly better survival was observed one year after surgery compared to patients receiving 2 immunosuppressive drugs alone. In patients receiving Zenapax with three other immunosuppressive drugs there was no difference in survival when compared with patients receiving the three immunosuppressive drugs alone.

"Traditionally, there has been a trade-off with anti-rejection drugs -- to increase the efficacy, we automatically increased side effects," said Flavio Vincenti, M.D., Professor of Clinical Medicine at the University of California, San Francisco. "Zenapax is a breakthrough therapy, because for the first time we have a drug that can significantly improve the efficacy of organ transplantation without an increase in drug toxicity."

Patients who undergo organ transplants must take special "anti-rejection" drugs to prevent their immune system from rejecting the organ. But unlike other drugs, which suppress the entire immune system and increase a patient's risk of infection, Zenapax blocks only those immune cells (known as T-cells) that are activated by a foreign substance - in this case a transplanted kidney. It does this by binding to specific receptors -- known as

TAC -- that are found on these activated cells. Because Zenapax is a humanized monoclonal antibody, the body is less likely to recognize it as foreign. Its efficacy is less likely to be limited by the body's natural response to non-human antibodies.

"The ability of Zenapax to selectively block certain T-cells from attacking the new

kidney -- without shutting down the entire immune system -- is a significant step in reducing the risk of organ rejection and improving survival rates," said John F. Neylan III, M.D., Associate Professor of Medicine and Medical Director of Transplant Outpatient Services at Emory University in Atlanta.

Development of Zenapax

Zenapax was created by Protein Design Labs (PDL) and developed and marketed by Roche Laboratories. PDL, a leading biotechnology firm in Mountain View, Calif., received fundamental U.S. and European patents covering humanized antibodies including Daclizumab, and a U.S. patent specifically for Daclizumab. Hoffmann-La Roche Ltd., Basel, Switzerland, and Hoffmann-La Roche Inc., Nutley, N.J. licensed exclusive worldwide rights to develop and market Zenapax from PDL.

In response to the vital needs of the transplant community, Roche will begin shipping Zenapax within a week of approval.

About organ transplants

Kidney rejection is a serious problem. In the past, rejection episodes after kidney transplants occurred about 30 percent to 50 percent of the time. However, recent data suggest that the rejection rate may be as low as 20 percent with the introduction of new immunosuppressive agents. 2 Acute rejection episodes may lead to a loss of the organ, which may result in a need for a second transplant, or force the patient to go back on dialysis.

According to the National Kidney Foundation, about 38,000 Americans are on a waiting list for kidney transplants, and only 12,000 per year will receive one.³"Obviously,

there is a major need for more donor organs," said Garabed Eknoyan, M.D., President of the National Kidney Foundation. "In the meantime, any reduction in the organ rejection rate is an important benefit, as it helps to alleviate the strain on the existing pool of donor organs."

For more information on kidney transplants and organ donation, call the National Kidney Foundation at 1-800-622-9010.

About Hoffmann-La Roche Inc.

Hoffmann-La Roche Inc. is a leading research-intensive pharmaceutical company that discovers, develops, manufactures and markets numerous important prescription drugs that improve, prolong and save the lives of patients with serious illnesses. Among the company's areas of therapeutic interest are virology, including HIV and AIDS, infectious diseases, cardiology, oncology, transplantation, dermatology and obesity.

The company provides a wide range of medications in the United States through its marketing and sales subsidiary, Roche Laboratories Inc. Headquartered in Nutley, N.J.,

both companies are members of the Basel, Switzerland-based Roche Group, a global leader in health care with principal businesses in pharmaceuticals, diagnostics, vitamins, and fragrances and flavors.

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