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Press Release

Advagraf™ (Extended Release Tacrolimus) Is Now Available In Canada For Kidney Transplant Patients

Markham, Ontario, April 14, 2008 - Advagraf™ (tacrolimus extended release capsules), marketed by Astellas Pharma Canada, Inc., has been approved by Health Canada for the prevention of organ rejection in patients receiving an allogeneic kidney transplant.[1] Patients who have received a kidney transplant now have access to a new once-a-day immunosuppressant therapy.

"Kidney transplantation is a life-altering experience which places a great deal of responsibility on a patient to take multiple medications at different times of the day to avoid compromising the kidney transplant," says Dr. Sita Gourishankar, a nephrologist in the University of Alberta's Department of Nephrology. "A once-daily anti-rejection therapy will be of considerable benefit and will help simplify the drug regimen required by post-transplant patients."

Extended release tacrolimus is a new formulation of Prograf® (tacrolimus twice daily), a leading immunosuppressant agent developed and marketed by Astellas.[2] Tacrolimus twice daily has been available in Canada since 1997. Both extended release tacrolimus and tacrolimus twice daily, which is indicated for prevention of kidney, liver and heart transplant rejection, are indicated for use concomitantly with corticosteroids and mycophenolate mofetil (MMF).[3]

"Because this is a once-a-day therapy, Advagraf helps streamline the number of medications patients need to take. This is an important step forward to improve long-term adherence to immunosuppressant therapy," says Barbara Reynolds, Director of New Product Development at Astellas Pharma Canada, Inc. "Astellas is very pleased to be able to offer the Canadian transplant community a new therapeutic option that not only helps prevent organ rejection, but that is more convenient for patients."

About Kidney Transplantation in Canada

According to the 2006 annual report published by the Canadian Institute for Health Information (CIHI), kidney transplantation is the most commonly-performed solid organ transplant procedure in Canada.[4] Report statistics show that at the end of 2004, there were 12,099 Canadians living with a functioning kidney transplant - a more than 50 per cent increase from 1995. The five-year organ transplant survival rate for recipients of living-donor kidneys was 97.5 per cent, compared to 89.1 per cent for those receiving a kidney from a deceased donor.[5]

The Importance of Adherence

Adherence to immunosuppressant therapy is critical to the prevention of organ rejection, yet as many as 28 per cent of adult renal transplant recipients and up to 50 per cent of adolescent recipients do not take their immunosuppressant as prescribed by their physicians.[6] Non-adherence is the third leading cause of graft loss after rejection and infection in renal transplant patients,[7] and is also associated with a higher risk of mortality[8] and with reduced functioning of the transplanted kidney.[9]

Research has demonstrated that a reduction in the number of doses of anti-rejection medication required on a daily basis can have a significant, positive impact on adherence.[10] Improving adherence was the primary thrust behind the development of once-daily extended release tacrolimus.

About Extended Release Tacrolimus

Extended release tacrolimus plus mycophenolate (MMF) and corticosteroids have been compared to cyclosporin plus MMF and corticosteroids in a phase III randomized, comparative trial in kidney transplant patients. Results show that efficacy failure at one year between the two drug regimens were similar for the treatment groups.[11]

In addition, data from an open label multicentre study show that kidney transplant recipients can be easily converted from tacrolimus twice daily to extended release tacrolimus. The majority of patients in this study did not require dosing adjustments from the previous visit over the two-year period. The study also reported that the once-daily dosing of extended release tacrolimus could potentially improve long-term adherence to immunosuppressant therapy.[12]

The most common adverse reactions among patients receiving extended release tacrolimus included infection, tremor, hypertension, decreased renal function, and gastrointestinal complaints of constipation, diarrhea, headache and insomnia. Many of these adverse reactions were mild and responded to a reduction in dosage.[13]

About Astellas Pharma Canada, Inc.

Astellas Pharma Canada, Inc. is highly focused on customers and their needs and is committed to making a difference in immunology. The company also seeks to develop breakthrough products in infectious disease, urology, dermatology and cardiovascular disease. Astellas Pharma Inc. is a pharmaceutical company dedicated to improving the health of people around the world through the provision of innovative and reliable pharmaceutical products. Astellas Pharma Canada, Inc., is one of the Astellas Group of companies in North America and an affiliate of Astellas Pharma Inc., located in Tokyo. The organization is committed to becoming a global pharmaceutical leader by combining outstanding R&D and marketing capabilities. Additional corporate information is available at www.astellas.com/ca.

For more information and to book interviews contact:

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