Press Release

For Immediate Release

Astellas Announces Health Canada's Approval of Advagraf® as a Once-daily Immunosuppressive Therapy for Liver Transplant Patients

Therapy helps simplify medication regimen for liver transplant recipients

June 19, 2014 – Markham, ON – Astellas Pharma Canada, Inc. ("Astellas"), a Canadian subsidiary of Tokyo-based Astellas Pharma Inc., announced today that Health Canada has now approved once-daily Advagraf® (tacrolimus extended release capsules) for prophylaxis of organ rejection in adult patients receiving liver transplants.[i] Tacrolimus extended release capsules are also approved in Canada for prophylaxis of organ rejection in adult patients receiving allogeneic kidney transplants.[1]

Liver transplantation is a complex and involved journey that starts when conservative therapies to treat liver disease fail, and is currently the only treatment for end-stage liver disease.[ii] As a life-saving measure, liver transplant allows for a diseased and poorly functioning liver to be replaced with a healthy donated liver.[iii] In Canada, over 5,000 liver deaths occur per year, yet there are not enough organs to meet the growing demand (with only about 400 transplants occurring annually).[2]

"Astellas is committed to supporting the life-long journey of liver transplant recipients, and in providing treatment options such as Advagraf to help maintain the health of the transplanted organ," says Michael Tremblay, President of Astellas. "Liver transplantation is an important, life-saving measure and now more than ever is a critical time for Canadians to register as organ donors."

Livers are the second-most transplanted organ in Canada. As with any organ transplant, all liver transplant patients must take anti-rejection medications for life to suppress the immune system and ultimately enable the recipient's body to accept the new liver without attacking it.[iv] In many instances, patients may experience a rejection episode following a transplant; however, 90 per cent of these events are reversed with minimal modifications to medication.[4]

"Transplant survival has improved dramatically over the last 20 years primarily because of the enhanced knowledge of how to use critical anti-rejection medications and our ability as transplant specialists to effectively monitor those patients who rely on them," says Dr. David Grant, Professor of Surgery, University of Toronto. "At the end of the day, it is about ensuring the best chance for graft and overall survival in our liver transplant patients, and medications, like Advagraf, help support the sustained health of a transplanted organ."

In Canada, liver transplantation is performed at 11 centres (Vancouver General Hospital, University of Alberta Hospital, London Health Sciences Centre (Children's Hospital), London Health Sciences Centre (University Campus), Hospital for Sick Children, Toronto General Hospital

(University Health Network), C.H. l'université de Montréal, St.-Luc, Hôpital Ste-Justine, Royal Victoria Hospital, McGill University Health Centre, and Queen Elizabeth II Health Sciences Centre). Livers for transplantation come from deceased donation (when an individual has been declared brain dead and with the consent of next of kin), or from a living donor (such as a relative or friend).[3]

About Tacrolimus Extended Release Capsules

Taken once-daily, tacrolimus extended release capsules provide a new, approved treatment option for individuals undergoing liver transplantation to help maintain the transplanted organ.[v] The primary endpoint in the phase III trial was the event rate of local biopsy-proven acute rejection (BPAR) within 24 weeks post-transplantation.[vi] Secondary endpoints were to determine the safety and tolerability of tacrolimus extended release capsules in liver transplant recipients.[6]

Tacrolimus extended release capsules were generally well-tolerated in clinical trials; the most common events among recipients who received tacrolimus extended release capsules (≥ 15% of patients in the tacrolimus extended release capsules group) were anemia, diarrhea, hyperglycemia, hypertension, pleural effusion, pyrexia, renal insufficiency and thrombocytopenia.[1] As with all anti-rejection medications, patients are carefully monitored for potential side effects and are treated accordingly.[4]

Stable liver transplant patients may be converted from Prograf (immediate release formulation) to Advagraf in combination with adrenal corticosteroids, based on equivalent tacrolimus whole blood trough concentrations.[1] Any changes in immunosuppressive therapy must be initiated by physicians experienced in immunosuppressive therapy and the management of transplant patients.[1]

About Astellas Pharma Canada, Inc.

Astellas Pharma Canada, Inc., headquartered in Markham, ON, is a Canadian affiliate of Tokyo-based Astellas Pharma Inc. Astellas is a pharmaceutical company dedicated to improving the health of people around the world through the provision of innovative and reliable pharmaceutical products. The organization is committed to becoming a global category leader in focused areas by combining outstanding R&D and marketing capabilities. In Canada, Astellas has an intense commercial focus on five therapeutic areas – Urology, Immunology, Infectious Disease, Dermatology and Oncology. For more information about Astellas Pharma Canada, Inc., please visit the corporate website: www.astellas.ca.

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References

[i] Advagraf Canadian Product Monograph, updated April 2014.
[ii] The Canadian Liver Foundation. Liver Disease in Canada: A Crisis in the Making – An Assessment of Liver Disease in Canada. March 2013.
[iii] The Canadian Liver Foundation. Liver Transplants. http://www.liver.ca/liver-disease/liver-transplants/. Accessed April 2014.
[iv] The Canadian Liver Foundation. What are the side effects of the anti-rejection medications? http://www.liver.ca/liver-disease/liver-transplants/how-do-transplants-work/. Accessed April 2014.
[v] Florman, S., et al. Conversion of Stable Liver Transplant Recipients from a Twice-Daily Prograf Regimen to a Once-Daily Modified Release Tacrolimus-Based Regimen. *Transplantation Proceedings,* 37, 1211–1213 (2005).
[vi] Trunecka, P., et al. Once-daily prolonged-release tacrolimus (Advagraf) versus twice-daily tacrolimus (Prograf) in liver transplantation. *American Journal of Transplantation.* 2010; 10: 2313–2323.