



For Immediate Release

Astellas Announces FDA Approval of ASTAGRAF XL™ (tacrolimus extended-release capsules) for the Prophylaxis of Organ Rejection in Adult Kidney Transplant Recipients

NORTHBROOK, III. July 19, 2013 – Astellas Pharma US, Inc. (“Astellas”), a U.S. subsidiary of Tokyo-based Astellas Pharma Inc. (Tokyo: 4503), announced today that the U.S. Food and Drug Administration (FDA) has approved ASTAGRAF XL™ (tacrolimus extended-release capsules) for the prophylaxis of organ rejection in patients receiving a kidney transplant with mycophenolate mofetil (MMF) and corticosteroids, with or without basiliximab induction.

"Each transplant recipient is different and requires a personalized treatment approach. The approval of ASTAGRAF XL marks an important milestone in post-transplant care as it provides physicians with a new treatment option for kidney transplant recipients," said Sef Kurstjens, M.D., PhD., chief medical officer, Astellas Pharma, Inc. "Astellas is pleased to continue our more than 20-year commitment to the field of transplant immunology."

ASTAGRAF XL is the first once-daily oral tacrolimus formulation available in the U.S. for kidney transplant recipients. ASTAGRAF XL offers a potentially promising treatment option for appropriate kidney transplant recipients as a core component of an immunosuppressive regimen for the prophylaxis of organ rejection.

The two primary, randomized, comparative phase 3 clinical studies to support FDA approval enrolled 1,093 patients (545 on tacrolimus extended-release) in the U.S., Europe, Canada, South America, Australia and South Africa. Astellas was granted marketing approval for tacrolimus extended-release capsules under the trade name Advagraf® in Europe in 2007 and under the trade name Graceceptor® in Japan in 2008. In total, tacrolimus extended-release capsules have been approved for use in 73 countries.

About ASTAGRAF XL (tacrolimus extended-release capsules)

ASTAGRAF XL extended-release capsules is a prescription medicine used with other medicines to help prevent organ rejection in people who have had a kidney transplant. ASTAGRAF XL is an extended-release capsule and is not the same as tacrolimus immediate-release capsules. Your doctor should decide what medicine is right for you.

ASTAGRAF XL is not for use with medicines called cyclosporine (Neoral®, Sandimmune®, Gengraf®). It is not known if ASTAGRAF XL is safe and effective when used with sirolimus (Rapamune®) in people who have had kidney transplants. It is not known if ASTAGRAF XL is safe and effective in children under 16 years of age who have had kidney transplants.

IMPORTANT SAFETY INFORMATION

What is the most important information I should know about ASTAGRAF XL?

ASTAGRAF XL can cause serious side effects, including:

- 1. Increased risk of cancer.** People who take ASTAGRAF XL have an increased risk of getting some kinds of cancer, including skin and lymph gland cancer (lymphoma).
- 2. Increased risk of infection.** ASTAGRAF XL is a medicine that affects your immune system and can lower the ability of your immune system to fight infections. Serious infections can happen in people receiving ASTAGRAF XL that can cause death. **Call your doctor right away if you have symptoms of**

an infection such as fever, sweats or chills, cough or flu-like symptoms, muscle aches, warm, red or painful areas on your skin.

3. Increased risk of death in females who have had a liver transplant. You should not take ASTAGRAF XL without talking to your doctor if you have had a liver transplant.

What should I tell my doctor before taking ASTAGRAF XL?

Before you take ASTAGRAF XL tell your doctor if you: plan to receive any live vaccines, have or have had liver, kidney or heart problems, or have any other medical conditions. Talk to your doctor if you are pregnant or plan to become pregnant. Tell your doctor If you are breastfeeding or plan to breastfeed. ASTAGRAF XL can pass into your breast milk. You and your doctor should decide if you will take ASTAGRAF XL or breastfeed. You should not do both.

Do not take ASTAGRAF XL if you are allergic to tacrolimus.

Tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins and herbal supplements. ASTAGRAF XL may affect the way other medicines work and other medicines may affect how ASTAGRAF XL works.

Know the medicines you take. Keep a list of them and show it to your doctor and pharmacist when you get a new medicine. Tell your doctor or pharmacist if there are any changes to the list of medicines you take.

How should I take ASTAGRAF XL?

- Take ASTAGRAF XL exactly as your doctor tells you to take it.
- Your doctor will tell you how much ASTAGRAF XL to take and when to take it
- Your doctor may change your dose of ASTAGRAF XL if needed. **Do not** stop taking or change your dose of ASTAGRAF XL without talking to your doctor.
- Take ASTAGRAF XL capsules whole. Do not break, crush, chew or dissolve before swallowing. If you cannot swallow ASTAGRAF XL capsules whole, tell your doctor.
- Take ASTAGRAF XL at the same time each morning, preferably on an empty stomach at least one hour before, or at least two hours after, you have eaten a meal.
- If you miss your dose of ASTAGRAF XL, it should be taken as soon as possible, but no longer than 14 hours after your regularly scheduled time. If longer than 14 hours, the missed dose should be skipped and the next dose should be taken the following morning at your regularly scheduled time. **Do not** take two doses at the same time.
- If you take too much ASTAGRAF XL, call your doctor or go to the nearest hospital emergency room right away.

What should I avoid while taking ASTAGRAF XL?

While you take ASTAGRAF XL you should not receive any live vaccinations such as flu vaccine through your nose, measles, mumps, rubella, polio by mouth, TB vaccine, yellow fever, chicken pox or typhoid. Avoid exposure to sunlight and UV light such as tanning machines. Wear protective clothing and use a sunscreen.

You should not eat grapefruit or drink grapefruit juice while taking ASTAGRAF XL.

You should not drink an alcoholic beverage when taking ASTAGRAF XL. It can increase your chances of getting serious side effects.

What are the possible side effects of ASTAGRAF XL?

- **See “What is the most important information I should know about ASTAGRAF XL?”**
- **Medication errors:** People who take ASTAGRAF XL have sometimes been given the wrong medicine, because some medicines have the same ingredient as ASTAGRAF XL. **You should check your ASTAGRAF XL when you get a new prescription medicine to make sure you have received the right medicine.** Call you doctor right away if you think you were given the wrong medicine. Ask your doctor or pharmacist if you are not sure what ASTAGRAF XL should look like.

ASTAGRAF XL may cause serious side effects, including: high blood sugar (diabetes), kidney problems, nervous system problems, high levels of potassium in your blood, high blood pressure, or heart problems such as changes in the electrical activity of your heart (QT prolongation). Call your doctor right away if you have any of these symptoms: frequent urination, increased thirst or hunger, blurred vision, confusion, drowsiness, loss of appetite, fruity smell on your breath, nausea, vomiting or stomach pain, coma, muscle tremors, numbness and tingling, headache, seizures or vision changes.

The most common side effects of ASTAGRAF XL in people receiving kidney transplant are: diarrhea, constipation, nausea, swelling of the hands, ankles or legs, tremors (shaking of the body) or low red blood cell count (anemia).

Tell your doctor if you have any side effect that bothers you or that does not go away. These are not all the possible side effects of ASTAGRAF XL. For more information, ask your doctor or pharmacist. Call your doctor for medical advice about side effects.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

For full prescribing information please visit www.astagrafxl.com.

About Astellas

Astellas Pharma US, Inc., located in Northbrook, Illinois, is a US 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. For more information about Astellas Pharma US, Inc., please visit our website at www.Astellas.us.

Astellas is a recognized leader in transplantation and has been committed to the field of immunology for more than 20 years. Dedicated to supporting the advancement of care for patients, Astellas continues to build upon its legacy and leadership in transplantation by investing in ongoing clinical research and new product development.

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