Pfizer Logo

Pfizer Wins RAPAMUNE® Patent Case in Delaware District Court

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(BUSINESS WIRE)--Pfizer Inc. said today that the United States District Court for the District of Delaware ruled that Pfizer’s patent covering a method for using sirolimus, the active ingredient in RAPAMUNE®, for the inhibition of organ transplant rejection is valid and infringed. The company brought a patent infringement action in April 2010 against the generic company Watson Laboratories, Inc—Florida (now known as Actavis) and three other Watson entities after Watson applied to the FDA to market a generic version of RAPAMUNE®. The Court’s decision prevents Watson from marketing its generic version of RAPAMUNE® in the U.S. before Pfizer’s patent expires, pending a possible appeal by Watson.

The patent at issue in the lawsuit is U.S. Patent No. 5,100,899, which including pediatric exclusivity, expires January 7, 2014. In response to the decision, Amy Schulman, Executive Vice President and General Counsel for Pfizer, said, “We are pleased with the Court’s decision, recognizing the validity of our patent."

In the United States, RAPAMUNE® is indicated for the prevention of organ transplant rejection in kidney transplant patients aged 13 years and older.

Important Safety Information

- **There is an increased risk of developing infections or certain cancers, especially lymphoma and skin cancers. Rapamune has not been shown to be safe and effective in people who have had liver or lung transplants. Serious complications and death may happen in people who take Rapamune after a liver or lung transplant. You should not take Rapamune if you have had a liver or lung transplant without talking with your doctor.**
- Do not take Rapamune if you know you are allergic to sirolimus or any of the other ingredients in Rapamune. Symptoms of an allergic reaction include swelling of your face, eyes, or mouth; trouble breathing or wheezing; throat tightness; chest pain or tightness; feeling dizzy or faint; and rash or peeling of your skin.
- Before taking Rapamune, tell your doctor if you have liver problems, skin cancer or it runs in your family, high cholesterol or triglycerides, are breastfeeding or plan to breastfeed, and are pregnant or plan to become pregnant. Women of childbearing potential should use effective birth control before therapy, during therapy, and for 12 weeks after Rapamune therapy has been stopped. Rapamune may interact with other medicines. Make sure that your doctor is aware of all prescription and over-the-counter drugs that you are taking, including vitamins, herbs, and nutritional supplements.
- Rapamune may cause swelling in your hands, feet, and in various tissues of your body. Call your doctor if you have trouble breathing.

- Rapamune may cause your wounds to heal slowly or not heal well resulting in redness, drainage, or opening of the wound.
- Rapamune may increase the levels of cholesterol and triglycerides (lipids or fat) in your blood. Your doctor should do blood tests to check your lipids during treatment with Rapamune. Your doctor may recommend treatment if your lipid levels become too high. Your lipid levels may remain high even if you follow your prescribed treatment plan.
- In patients taking Rapamune with cyclosporine, decreased kidney function has been observed. Your doctor will regularly check your kidney function.
- Rapamune may increase protein in your urine. Your doctor may monitor you for abnormal protein in your urine from time to time.
- Rapamune may increase your risk for viral infections. Certain viruses can live in your body and cause active infections when your immune system is weak. One of these viruses, BK virus, can affect how your kidney works and cause your transplanted kidney to fail. A certain virus can cause a rare serious brain infection called Progressive Multifocal Leukoencephalopathy causing death or severe disability.
- Rapamune may cause potentially life-threatening lung or breathing problems. Symptoms may include coughing, shortness of breath, or difficulty breathing.
- When Rapamune is taken with cyclosporine or tacrolimus, you may develop a blood clotting problem resulting in unexplained bleeding or bruising.
- Common side effects associated with Rapamune include high blood pressure, pain (including stomach and joint pain), diarrhea, headache, fever, urinary tract infection, low red blood cell count (anemia), nausea, and low platelet count (cells that help blood to clot). If you experience any side effects, contact your doctor.

Indications and Usage

RAPAMUNE® (sirolimus) is indicated for the prevention of organ rejection in kidney transplant patients aged 13 years or older. Blood levels of sirolimus should be checked in all patients taking Rapamune.

- **In patients at low to moderate risk of acute rejection**, it is recommended that Rapamune be used initially in combination with cyclosporine and corticosteroids; cyclosporine should be withdrawn approximately 3 months after transplantation. Cyclosporine withdrawal has not been studied in patients who have had severe acute rejection prior to cyclosporine withdrawal, those who require dialysis or have a high serum creatinine, Black patients, patients receiving a repeat kidney transplant, patients receiving other transplanted organs besides the kidney transplant, or patients with antibodies that may be directed against the kidney transplant.
- **In patients at high risk of acute rejection** (defined as Black patients and/or patients receiving a repeat kidney transplant who lost a previous kidney transplant from rejection and/or patients with high levels of antibodies that may be directed against the kidney transplant), it is recommended that Rapamune be used in combination with cyclosporine and corticosteroids for the first year following transplantation. The safety and efficacy of this combination in high-risk patients have not been studied beyond one year; therefore, after the first year, adjustments to the immunosuppressive regimen may be considered by your doctor.

In pediatric patients, the safety and efficacy of Rapamune have not been established in kidney transplant patients less than 13 years old, or in patients less than 18 years old who are considered at high risk of acute rejection.

- The safety and efficacy of Rapamune without cyclosporine in newly transplanted kidney patients have not been established.

- The safety and efficacy of changing from either cyclosporine or tacrolimus to Rapamune in maintenance kidney transplant patients have not been established.

Please see full Prescribing Information for Rapamune, including Boxed Warning and Medication Guide here.

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