Pfizer Announces Top-Line Results Of Phase 3B/4 Study Of RAPAMUNE® (sirolimus) In Renal Transplant Recipients

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Pfizer Inc. (NYSE:PFE) announced today top-line results from a Phase 3B/4 study of RAPAMUNE® (sirolimus) evaluating kidney transplant patients who transitioned from tacrolimus-based therapy (TAC) to RAPAMUNE® 3 to 5 months after transplant. The primary endpoint of the study was not achieved as there was not a statistically significant difference in renal function improvement between patients who continued receiving TAC and those who switched to RAPAMUNE®.

For patients who were switched to RAPAMUNE®, 33.7% of patients achieved the primary endpoint of a ≥ 5 ml/min/1.73m2 renal function improvement based on glomerular filtration rate (GFR) from randomization to 24 months post-transplantation and 42.3% of patients continuing to take TAC achieved the primary endpoint (p=0.239).

The study was an open-label, randomized, comparative, multi-center, multi-national study conducted in Europe, Latin America, North America, and the Pacific Region. There were 256 subjects randomized at 3 to 5 months after transplant, with two subjects not receiving any medication. Group I included 131 subjects receiving RAPAMUNE®; the dose was adjusted to sirolimus blood levels of 7-15 ng/mL during the first year post-transplantation and 5-15 ng/mL thereafter. Group II, the control group, included 123 subjects who continued receiving the same TAC-based treatment that was being administered prior to randomization. Subjects in both groups were evaluated at a pre-randomization visit, at the day of randomization, 4-weeks after randomization, and 6-, 12-, 18- and 24-months post transplantation.

The study also evaluated the safety of RAPAMUNE® and the adverse events observed in the study were consistent with the known safety profile of RAPAMUNE®. The results of this study are expected to be submitted for presentation at upcoming scientific congresses and for publication in peer-reviewed medical journals.

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

Important RAPAMUNE® 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.

RAPAMUNE® 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, including Medication Guide and Boxed Warning, available at www.RAPAMUNE.com.

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