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Press Release

Hikma launches a generic version of Afinitor® Tablets, 2.5mg, 5mg, 7.5mg

London, June 11, 2020 – Hikma Pharmaceuticals PLC (Hikma, Group), the multinational generic pharmaceutical company, has launched Everolimus Tablets, 2.5mg, 5mg, and 7.5mg, the generic equivalent to Afinitor®,[1] in the United States through its US affiliate, Hikma Pharmaceuticals USA Inc.

Everolimus is indicated for the treatment of adult patients with advanced renal cell carcinoma (RCC) after failure of treatment with Sunitinib or Sorafenib. Everolimus is also indicated for the treatment of adult patients with renal angiomyolipoma and tuberous sclerosis complex (TSC), not requiring immediate surgery.

“We are very pleased to add a generic version of Afinitor® to our portfolio and improve patient access to this important medicine,” said Brian Hoffmann, President of Generics. “Building a portfolio of more complex, differentiated products is a key element of our strategy and this launch demonstrates our ability to successfully litigate and provide patients with high-quality, affordable medicines.”

According to IQVIA, US sales of Everolimus Tablets, 2.5mg, 5mg and 7.5mg, were approximately $435 million in the 12 months ending April 2020.

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About Hikma
(LSE: HIK) (NASDAQ Dubai: HIK) (OTC: HKMPY) (rated Ba1/stable Moody's and BB+/positive S&P)

Hikma helps put better health within reach every day for millions of people in more than 50 countries around the world. For more than 40 years, we've been creating high-quality medicines and making them accessible to the people who need them. Headquartered in the UK, we are a global company with a local presence across the United States (US), the Middle East and North Africa (MENA) and Europe,

[1] Afinitor® is a registered trademark of Novartis AG

and we use our unique insight and expertise to transform cutting-edge science into innovative solutions that transform people's lives. We're committed to our customers, and the people they care for, and by thinking creatively and acting practically, we provide them with a broad range of branded and non-branded generic medicines. Together, our 8,600 colleagues are helping to shape a healthier world that enriches all our communities. We are a leading licensing partner, and through our venture capital arm, are helping bring innovative health technologies to people around the world. For more information, please visit: www.hikma.com

Important Safety Information for Everolimus Tablets, 2.5mg, 5mg, and 7.5mg:

Contraindications
Everolimus is contraindicated in patients with clinically significant hypersensitivity to everolimus or to other rapamycin derivatives.

Warnings and Precautions
Non-Infectious Pneumonitis
Non-infectious pneumonitis is a class effect of rapamycin derivatives. Fatal outcomes have been observed. The development of pneumonitis has been reported even at a reduced dose. For Grade 2 to 4 non-infectious pneumonitis, withhold or permanently discontinue Everolimus based on severity. Advise patients to promptly report any new or worsening respiratory symptoms.

Infections
Localized and systemic infections including pneumonia, mycobacterial infections, other bacterial infections, invasive fungal infections (eg, aspergillosis, candidiasis, or pneumocystis jiroveci pneumonia [PJP]) and viral infections (eg, reactivation of hepatitis B virus), some fatal, have occurred in patients treated with Everolimus. Complete treatment of preexisting invasive fungal infections prior to starting treatment, and monitor for signs and symptoms of infection. Withhold or permanently discontinue Everolimus based on severity of infection, and administer prophylaxis for PJP when concomitant use of corticosteroids or other immunosuppressive agents are required.

Severe Hypersensitivity Reactions
Hypersensitivity reactions to Everolimus have been observed and include anaphylaxis, dyspnea, flushing, chest pain and angioedema. Permanently discontinue Everolimus if clinically significant hypersensitivity develops.

Angioedema With Concomitant Use of Angiotensin-Converting Enzyme (ACE) Inhibitors
Patients taking concomitant ACE inhibitors with Everolimus may be at increased risk for angioedema. Permanently discontinue Everolimus in patients who develop angioedema.

Stomatitis
If stomatitis occurs, mouthwashes and/or other topical treatments are recommended. Avoid alcohol-, hydrogen peroxide-, iodine- or thyme-containing products, as they may exacerbate stomatitis. Do not administer antifungal agents, unless fungal infection has been diagnosed.

Renal Failure
Cases of renal failure, some with a fatal outcome, have occurred in patients taking Everolimus. Monitor renal function prior to starting Everolimus and annually thereafter. Monitor renal function at least every 6 months in patients with additional risk factors for renal failure.

Risk of Impaired Wound Healing
Everolimus has the potential to adversely affect wound healing.

Withhold Everolimus for at least 1 week prior to elective surgery. Do not administer for at least 2 weeks following major surgery and until adequate wound healing. The safety of resumption of treatment upon resolution of wound healing complications has not been established.

Metabolic Disorders
If possible, achieve optimal glucose and lipid control prior to starting Everolimus. In non-diabetic patients, monitor fasting serum glucose prior to starting Everolimus and annually thereafter. Monitor fasting serum glucose more frequently in diabetic patients. Monitor the lipid profile in all patients prior to starting Everolimus and annually thereafter. For Grade 3 to 4 metabolic events, withhold or permanently discontinue Everolimus based on severity.

Myelosuppression
Anemia, lymphopenia, neutropenia and thrombocytopenia have been reported in patients taking Everolimus. Monitor complete blood count prior to starting Everolimus every 6 months for the first year of treatment. Withhold or permanently discontinue Everolimus based on severity of myelosuppression.

Risk of Infection or Reduced Immune Response With Vaccination
The safety of immunization with live vaccines during Everolimus therapy has not been studied. Avoid the use of live vaccines and close contact with individuals who have received live vaccines during treatment with Everolimus. Due to the potential increased risk of infection or reduced immune response with vaccination, complete the recommended childhood series of vaccinations according to American Council on Immunization Practices (ACIP) guidelines prior to the start of therapy. An accelerated vaccination schedule may be appropriate. For more information, see the full Prescribing Information for Everolimus tablets.

Embryo-Fetal Toxicity
Everolimus can cause fetal harm when administered to a pregnant woman. Advise pregnant women of the potential risk to a fetus. Advise female patients of reproductive potential to avoid becoming pregnant and to use effective contraception during treatment with Everolimus and for 8 weeks after the last dose. Advise male patients with female partners of reproductive potential to use effective contraception during treatment with Everolimus and for 4 weeks after the last dose.

Adverse Reactions
The following serious adverse reactions are discussed in detail in the full Prescribing Information for Everolimus tablets:

- Non-infectious Pneumonitis
- Infections
- Severe Hypersensitivity Reactions
- Angioedema with Concomitant Use of ACE Inhibitors
- Stomatitis
- Renal Failure
- Impaired Wound Healing
- Metabolic Disorders
- Myelosuppression

The most common (≥30%) adverse reactions observed in patients treated with Everolimus in a renal cell carcinoma trial were stomatitis, infections, asthenia, fatigue, cough and diarrhea.

The most common (≥30%) adverse reaction observed in a study of 118 patients with renal angiomyolipoma as a feature of TSC (n=113) or sporadic lymphangioleiomyomatosis (n=5) treated with Everolimus was stomatitis.

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According to updated safety information from 112 patients treated with Everolimus for a median duration of 3.9 years, the most common (≥30%) adverse reactions and selected laboratory abnormalities observed were increased partial thromboplastin time, increased prothrombin time, decreased fibrinogen and urinary tract infection.

Drug Interactions

- Avoid the concomitant use of P-gp and strong CYP3A4 inhibitors; reduce the dose for patients taking Everolimus with a P-gp and moderate CYP3A4 inhibitor as recommended.
- Increase the dose for patients taking Everolimus with a P-gp and strong CYP3A4 inducer as recommended.
- Avoid the concomitant use of ACE inhibitors with Everolimus.

Use in Specific Populations

Pregnancy

Everolimus can cause fetal harm when administered to a pregnant woman. Advise pregnant women of the potential risk to the fetus.

Lactation

Because of the potential for serious adverse reactions in breastfed infants from Everolimus, advise lactating women not to breastfeed during treatment with Everolimus and for 2 weeks after the last dose.

Females and Males of Reproductive Potential

Verify the pregnancy status of females of reproductive potential prior to starting Everolimus. Everolimus can cause fetal harm when administered to pregnant women. Advise females of reproductive potential to use effective contraception during treatment with Everolimus and for 8 weeks after the last dose. Advise male patients with female partners of reproductive potential to use effective contraception during treatment with Everolimus and for 4 weeks after the last dose. Everolimus may impair fertility in female patients. Cases of reversible azoospermia have been reported in male patients taking Everolimus.

Pediatric Use

The safety and effectiveness of Everolimus have not been established in pediatric patients with renal cell carcinoma or TSC-associated renal angiomyolipoma.

Geriatric Use

No overall differences in safety or effectiveness were observed between elderly and younger patients.

Hepatic Impairment

Everolimus exposure may increase in patients with hepatic impairment; reduce the dose as recommended.

For more information, please see the Medication Guide and full Prescribing Information.

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

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