When advanced kidney cancer treatments fail (sunitinib or sorafenib),

**AFINITOR® (everolimus) Tablets may be another option**

*AFINITOR® (everolimus) Tablets* is a prescription medicine used to treat adults with advanced kidney cancer (renal cell carcinoma or RCC) when certain other medicines (sunitinib or sorafenib) have not worked.

Please see Important Safety Information throughout, with Brief Summary of Important Safety Information on pages 10-14.

Click here for full Prescribing Information, including Patient Information.
What You Should Know About Advanced Kidney Cancer

Advanced kidney cancer occurs when cancer cells in the kidneys spread to other parts of the body. Anyone can develop advanced kidney cancer.

Knowing you have advanced kidney cancer is not easy. You have tried other medicines but, now, they have stopped working. Although you may be scared, talk to your health care provider. There may be other treatment options that are right for you.

This brochure will help you understand your disease. It will also describe a medicine that may keep your cancer from getting worse.

Understanding the stages of kidney cancer

Staging is a tool health care providers use to describe your cancer’s growth and the spread of cancer cells. This information helps them decide the best treatment option for you.

There are four stages of kidney cancer: stage I, stage II, stage III, and stage IV. Stage IV is also called advanced kidney cancer. In this stage, treatment may include surgery and medicines.

Important Safety Information

Do not take AFINITOR® (everolimus) Tablets if you have had a severe allergic reaction to everolimus. You should tell your health care provider before taking AFINITOR if you are allergic to sirolimus (Rapamune®) or temsirolimus (Torisel®).

*Rapamune and Torisel are registered trademarks of Pfizer Inc.*

*Please see Important Safety Information throughout, with Brief Summary of Important Safety Information on pages 10-14.*

*Click here for full Prescribing Information, including Patient Information.*
Stage I
Fairly small tumor of 7 centimeters (about 2-3/4 inches) or smaller that has not spread beyond the kidney

Stage II
Tumor larger than 7 centimeters that has not spread beyond the kidney

Stage III
Tumor has grown a little beyond the kidney, and/or cancer cells have entered the lymph nodes or large blood vessels close to the kidney

Stage IV (advanced)
Tumor has grown beyond the kidney and the tissue around it, and/or cancer cells have entered lymph nodes close by or have spread to other parts of the body (called "metastasis")
How Advanced Kidney Cancer Progresses

Cancer progression

When kidney cancer is widely spread in the body, treatment cannot eliminate it. But there are treatments that may shrink the cancer or stop it from growing, often for months at a time or longer. However, cancer cells eventually “learn” how to grow, despite the treatment, and the tumor begins to grow again. This is called cancer progression.

Cancer progression may be challenging emotionally, because a treatment that was working is no longer working. However, there are now many different types of treatments for kidney cancer. When progression occurs, you may be able to switch to another treatment.

Important Safety Information (cont)

AFINITOR® (everolimus) Tablets can cause serious side effects; some of these side effects can be severe and can even lead to death. If patients experience these side effects, they may need to stop taking AFINITOR for a while or use a lower dose. Patients should follow their health care provider’s instructions.

Please see Important Safety Information throughout, with Brief Summary of Important Safety Information on pages 10-14. Click here for full Prescribing Information, including Patient Information.
Treating advanced kidney cancer

Every person is different, and treatment differs from patient to patient. Treatment options for advanced kidney cancer often follow these steps:

<table>
<thead>
<tr>
<th>Surgery</th>
<th>Removing all or part of the kidney</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>First-line therapy</strong></td>
<td>The first treatment used to treat the advanced cancer. It is also called <em>primary therapy</em> or <em>primary treatment</em></td>
</tr>
<tr>
<td><strong>Second-line therapy</strong></td>
<td>Treatment that is given when first-line therapy does not work or stops working</td>
</tr>
<tr>
<td><strong>Third-line therapy and beyond</strong></td>
<td>Treatment that is given when second-line therapy has failed to work or stops working</td>
</tr>
</tbody>
</table>
Please see Important Safety Information throughout, with Brief Summary of Important Safety Information on pages 10-14. Click here for full Prescribing Information, including Patient Information.
About AFINITOR® (everolimus) Tablets

AFINITOR® (everolimus) Tablets is a medicine that your health care provider can prescribe when certain other medicines (sunitinib or sorafenib) have stopped working.

How AFINITOR works

AFINITOR works differently than sunitinib or sorafenib, because AFINITOR is an mTOR (or mammalian target of rapamycin) inhibitor. Other medicines (sunitinib or sorafenib) work by blocking a chemical in the body called vascular endothelial growth factor, or VEGF.

AFINITOR may help:

- Slow the growth and spread of kidney cancer cells
- Restrict cancer cells from getting the nutrition they need to grow
- Slow the blood vessels from growing and supplying the tumor with blood

This activity was shown in laboratory settings, as well as in living animals and humans.

Important Safety Information (cont)

Serious side effects include:

**Lung or Breathing Problems:** In some patients, lung or breathing problems may be severe and can even lead to death. Patients should tell their health care provider right away if they have any of these symptoms: new or worsening cough, shortness of breath, chest pain, difficulty breathing, or wheezing.

Please see Important Safety Information throughout, with Brief Summary of Important Safety Information on pages 10-14.

Click here for full Prescribing Information, including Patient Information.
**How AFINITOR® (everolimus) Tablets Was Studied**

**Who was included in AFINITOR clinical studies?**

AFINITOR® (everolimus) Tablets was studied in 416 patients with advanced kidney cancer. These patients had already taken sunitinib and/or sorafenib, and then their cancer progressed.

The main goal of the study was to measure the length of time patients lived without their disease getting worse while taking AFINITOR. This is also called progression-free survival (PFS) time.

In this study, some patients were given AFINITOR. Others were given a placebo. A placebo is a pill with no medicine in it.

---

**All patients studied had taken other medicine(s) (sunitinib and/or sorafenib) for their advanced kidney cancer before they took AFINITOR.**

1. Some patients had tried 1 medicine
2. Some patients tried 2 medicines (1 treatment, and then another treatment when the medicine stopped working)

---

Please see Important Safety Information throughout, with Brief Summary of Important Safety Information on pages 10-14. Click here for full Prescribing Information, including Patient Information.
How did patients do in AFINITOR clinical studies?

AFINITOR® (everolimus) Tablets delayed advanced kidney cancer from getting worse by 3 months longer than placebo

AFINITOR results 4.9 months

Placebo results 1.9 months

These numbers are based on a median, which means that half of the patients on each treatment did better than the results presented, and half did worse.

Important Safety Information (cont)

Infections: AFINITOR may make patients more likely to develop an infection, such as pneumonia, or a bacterial, fungal, or viral infection. Viral infections may include reactivation of hepatitis B in people who have had hepatitis B in the past. In some people, these infections may be severe and can even lead to death. Patients may need to be treated as soon as possible.

Please see Important Safety Information throughout, with Brief Summary of Important Safety Information on pages 10-14.

Click here for full Prescribing Information, including Patient Information.
Summary of Important Information

What is AFINITOR® (everolimus) Tablets used for?
AFINITOR® (everolimus) Tablets is a prescription medicine used to treat adults with advanced kidney cancer (renal cell carcinoma or RCC) when certain other medicines (ie, Sutent® [sunitinib] or Nexavar® [sorafenib]) have not worked.

What is the most important information I should know about AFINITOR?
AFINITOR can cause serious side effects; some of these side effects can be severe and can even lead to death. If patients experience these side effects, they may need to stop taking AFINITOR for a while or use a lower dose. Patients should follow their health care provider’s instructions. Serious side effects include:

Lung or Breathing Problems: In some patients, lung or breathing problems may be severe and can even lead to death. Patients should tell their health care provider right away if they have any of these symptoms: new or worsening cough, shortness of breath, chest pain, difficulty breathing, or wheezing.

Infections: AFINITOR may make patients more likely to develop an infection, such as pneumonia, or a bacterial, fungal, or viral infection. Viral infections may include reactivation of hepatitis B in people who have had hepatitis B in the past. In some people, these infections may be severe and can even lead to death. Patients may need to be treated as soon as possible. Patients should tell their health care provider right away if they have a temperature of 100.5°F or above, have chills, or do not feel well. Symptoms of hepatitis B or infection may include the following: fever, chills, skin rash, joint pain and inflammation, tiredness, loss of appetite, nausea, pale stools or dark urine, yellowing of the skin, or pain in the upper right side of the stomach.

Sutent is a registered trademark of Pfizer Inc. Nexavar is a registered trademark of Bayer Aktiengesellschaft.

Please see Important Safety Information throughout, with Brief Summary of Important Safety Information on pages 10-14. Click here for full Prescribing Information, including Patient Information.
Severe Allergic Reactions: Severe allergic reactions can happen in people who take AFINITOR® (everolimus) Tablets. Call your health care provider or get medical help right away if you get signs and symptoms of a severe allergic reaction, including rash, itching, hives, flushing, trouble breathing or swallowing, chest pain, or dizziness.

Angioedema: Patients who take an angiotensin-converting enzyme (ACE) inhibitor medicine during treatment with AFINITOR are at a possible increased risk for a type of allergic reaction called angioedema. Talk with your health care provider before taking AFINITOR if you are not sure if you take an ACE inhibitor medicine. Get medical help right away if you have trouble breathing or develop swelling of your tongue, mouth, or throat during treatment with AFINITOR.

Kidney Failure: Patients taking AFINITOR may develop kidney failure. In some people, this may be severe and can even lead to death. Patients should have tests to check their kidney function before, and during their treatment with AFINITOR.

Delayed Wound Healing: AFINITOR can cause incisions to heal slowly or not heal well. Call your health care provider right away if your incision is red, warm, or painful; if you have blood, fluid, or pus in your incision; if your incision opens up; or if your incision swells.

Increased Blood Sugar and Fat (cholesterol and triglycerides) Levels in Blood: Your health care provider should do blood tests to check your fasting blood sugar, cholesterol, and triglyceride levels in the blood before you start and during treatment with AFINITOR.

Decreased Blood Cell Counts: AFINITOR can cause you to have decreased red blood cells, white blood cells, and platelets. Your health care provider should do blood tests to check your blood cell counts before you start and during treatment with AFINITOR.
Who should not take AFINITOR® (everolimus) Tablets?

Do not take AFINITOR® (everolimus) Tablets if you have had a severe allergic reaction to everolimus. You should tell your health care provider before taking AFINITOR if you are allergic to sirolimus (Rapamune®) or temsirolimus (Torisel®).

What should I tell my health care provider before taking AFINITOR?

Before taking AFINITOR, tell your health care provider about all your medical conditions, including if you:

- Have or have had kidney problems
- Have or have had liver problems
- Have diabetes or high blood sugar
- Have high blood cholesterol levels
- Have any infections
- Previously had hepatitis B
- Are scheduled to receive any vaccinations. You should not receive a live vaccine or be around people who have recently received a live vaccine during your treatment with AFINITOR. If you are not sure about the type of vaccine, ask your health care provider
- Are pregnant or could become pregnant, or have a partner who could become pregnant. AFINITOR can cause harm to your unborn baby. If you are a woman who is able to become pregnant, you should use effective birth control while using AFINITOR and for 8 weeks after your last dose. If you are a male with a woman partner, you should use effective birth control during treatment and for 4 weeks after your last dose. Talk to your health care provider about birth control options while taking AFINITOR
- Are breastfeeding or plan to breastfeed. Do not breastfeed during treatment and for 2 weeks after your last dose
- Are about to have surgery, if you have had a recent surgery, or if you have an unhealed wound

Rapamune and Torisel are registered trademarks of Pfizer Inc.

Please see Important Safety Information throughout, with Brief Summary of Important Safety Information on pages 10-14.

Click here for full Prescribing Information, including Patient Information.
What other medications might interact with AFINITOR® (everolimus) Tablets?

Tell your health care provider about all of the medicines you take, including prescription and nonprescription medicines, vitamins, and herbal supplements. Using AFINITOR® (everolimus) Tablets with certain other medicines can cause serious side effects. Keep a list of medicines you take, and show it to your health care provider when you get a new medicine. Especially tell your health care provider if you take St John’s wort (*Hypericum perforatum*), medicines that weaken your immune system (your body’s ability to fight infections and other problems), or medicines for:

- Fungal infections
- Bacterial infections
- Tuberculosis
- Seizures
- HIV-AIDS
- Heart conditions or high blood pressure

If you are taking any medicines for the conditions listed above, your health care provider might need to prescribe a different medicine or your dose of AFINITOR may need to be changed. Tell your health care provider before you start taking any new medicine.

What are other side effects of AFINITOR?

**Common Side Effects:** Common side effects include mouth ulcers. AFINITOR can cause mouth ulcers and sores. When you start treatment with AFINITOR, your health care provider may tell you to also start a prescription mouthwash to reduce the likelihood of getting mouth ulcers or sores and to reduce their severity. Follow your health care provider’s instructions on how to use this prescription mouthwash. Tell your health care provider if you have pain, discomfort, or open sores in your mouth. Your health care provider may tell you to restart this mouthwash or to use a special mouthwash or gel that does not contain alcohol, hydrogen peroxide, iodine, or thyme.
Other common side effects include:

- Infections
- Rash
- Feeling weak or tired
- Diarrhea
- Swelling of arms, hands, feet, ankles, face, or other parts of the body
- Stomach (abdominal) pain
- Nausea
- Fever
- Cough
- Headache
- Decreased appetite

Other side effects that may occur with AFINITOR® (everolimus) Tablets:

- Absence of menstrual periods (menstruation). You may miss 1 or more menstrual periods. Tell your health care provider if this happens
- AFINITOR may affect fertility in females and males, and may affect your ability to become pregnant if you are female or your ability to father a child if you are male. Talk to your health care provider if this is a concern for you

Tell your health care provider if you have any side effect that bothers you or does not go away.

**General information about the safe and effective use of AFINITOR**

These are not all the possible side effects of AFINITOR. For more information, ask your health care provider 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.

**Managing mouth ulcers and sores**

Talk with your health care provider if you have mouth ulcers or sores. He or she may tell you to use a mouthwash or mouth gel that does not contain alcohol, peroxide, iodine, or thyme.

Please see Important Safety Information throughout, with Brief Summary of Important Safety Information on pages 10-14.

Click here for full Prescribing Information, including Patient Information.
Use this space to write down the names of the prescription and nonprescription medicines, vitamins, and herbal supplements you take or are thinking of taking. Show this list to your health care provider before taking AFINITOR® (everolimus) Tablets.

I am taking the following:

____________________________________________________________________

____________________________________________________________________

____________________________________________________________________

____________________________________________________________________

____________________________________________________________________

____________________________________________________________________

____________________________________________________________________

____________________________________________________________________

____________________________________________________________________

____________________________________________________________________

____________________________________________________________________

____________________________________________________________________

____________________________________________________________________

____________________________________________________________________

____________________________________________________________________

____________________________________________________________________

____________________________________________________________________

____________________________________________________________________

Please see Important Safety Information throughout, with Brief Summary of Important Safety Information on pages 10-14.

Click here for full Prescribing Information, including Patient Information.
How to Take AFINITOR® (everolimus) Tablets

How should I take AFINITOR?

- Your health care provider will prescribe the dose of AFINITOR® (everolimus) Tablets that is right for you
- Take AFINITOR exactly as your health care provider tells you to
- Your health care provider may change your dose of AFINITOR or tell you to temporarily interrupt dosing, if needed
- Use scissors to open the blister pack
- Swallow AFINITOR tablets whole with a glass of water. Do not take any tablet that is broken or crushed
- Take AFINITOR 1 time each day at about the same time
- Take AFINITOR the same way each time, either with food or without food
- If you take too much AFINITOR, contact your health care provider or go to the nearest hospital emergency room right away. Take the pack of AFINITOR with you
- If you miss a dose of AFINITOR, you may still take it if it is less than 6 hours after the time you normally take it. If it is more than 6 hours after you normally take your AFINITOR, skip the dose for that day. The next day, take AFINITOR at your usual time. Do not take 2 doses to make up for a missed dose. If you are not sure about what to do, call your health care provider
- You should have blood tests before you start AFINITOR and as needed during your treatment. These will include tests to check your blood cell count, kidney and liver function, cholesterol, and blood sugar levels

Please see Important Safety Information throughout, with Brief Summary of Important Safety Information on pages 10-14. Click here for full Prescribing Information, including Patient Information.
How to Store AFINITOR® (everolimus) Tablets

AFINITOR® (everolimus) Tablets comes in foil-wrapped blister packaging. This protects the tablets from moisture and light. You should always:

- Store AFINITOR at room temperature, between 68°F to 77°F (20°C to 25°C)
- Keep AFINITOR in the pack it comes in
- Open the blister pack just before taking AFINITOR
- Keep AFINITOR dry and away from light
- Do not use AFINITOR that is out of date or no longer needed
- Keep AFINITOR and all medicines out of the reach of children

Please see Important Safety Information throughout, with Brief Summary of Important Safety Information on pages 10-14.

Click here for full Prescribing Information, including Patient Information.
Use the space below to write down any questions you may have or how you feel after starting treatment. Share this list with your health care provider.

_____________________________________________________________________________
_____________________________________________________________________________
_____________________________________________________________________________
_____________________________________________________________________________
_____________________________________________________________________________
_____________________________________________________________________________
_____________________________________________________________________________
_____________________________________________________________________________

Please see Important Safety Information throughout, with Brief Summary of Important Safety Information on pages 10-14. Click here for full Prescribing Information, including Patient Information.
Support During Your Treatment

Financial support
Financial support may be available for some patients.

Universal Co-Pay Program
Novartis Oncology offers access to financial assistance for almost all Novartis Oncology products. You may be eligible for immediate co-pay savings on your next prescription:

• Commercially insured patients pay $0 per month
• Novartis will pay the remaining co-pay, up to $15,000 per calendar year*

* Limitations apply. See program terms and conditions at www.CoPay.NovartisOncology.com. Offer is not valid under Medicare, Medicaid, or any other federal or state program. Novartis reserves the right to rescind, revoke, or amend this program without notice.

See if you are eligible at www.CoPay.NovartisOncology.com, or call 1-877-577-7756.

Patient Assistance Now Oncology
Novartis Oncology is committed to helping you get the medicines you need. Getting access to medications can sometimes be difficult or confusing. Patient Assistance Now Oncology (PANO) offers tools and support designed specifically to help make that process easier.

You can get information about our PANO support program in 2 ways:

• Call 1-800-282-7630 to speak with a member of our knowledgeable staff dedicated to making access as simple and convenient as possible; or
• Visit our website at: www.OncologyAccessNow.com/patient

Please see Important Safety Information throughout, with Brief Summary of Important Safety Information on pages 10-14. Click here for full Prescribing Information, including Patient Information.