A treatment option for people living with advanced pancreatic neuroendocrine tumors

AFINITOR® (everolimus) Tablets

AFINITOR is a prescription medicine used to treat adults with a type of pancreatic cancer known as pancreatic neuroendocrine tumor (PNET) that has progressed and cannot be treated with surgery.

AFINITOR is not for use in people with carcinoid tumors that actively produce hormones.

Important Safety Information

Do not take AFINITOR 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®).

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.

Please see additional Important Safety Information on pages 7-9 and 11-13, and click here for full Prescribing Information for AFINITOR, including Patient Information.
Advanced pancreatic neuroendocrine tumors (PNET) are a rare type of cancer that can be hard to diagnose. Usually, at the time they are diagnosed, the tumors are in an advanced stage.

AFINITOR® (everolimus) Tablets is a prescription medicine used to treat adults with a type of pancreatic cancer known as pancreatic neuroendocrine tumor (PNET) that has progressed and cannot be treated with surgery.

AFINITOR is not for use in people with carcinoid tumors that actively produce hormones. This booklet will help you learn more about advanced PNET and how AFINITOR can help. You will also find resources and support that will help guide you going forward.

Table of contents

What is advanced PNET? ................................................................. 4
Your AFINITOR treatment .................................................. 6
Before taking AFINITOR ........................................................... 9
How should AFINITOR be taken? ............................................ 10
What are the possible side effects of AFINITOR? .................. 12
Your treatment team .............................................................. 14
The AFINITOR Patient Support Program ................................ 15
Glossary ................................................................................... 18

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Neuroendocrine tumors can occur in different parts of the body. When they originate in the pancreas, they are called PNET. At the advanced stage, the disease has progressed and the tumor cells have spread to other organ sites.

What are neuroendocrine cells?
 Neuroendocrine cells are special cells in your body that can affect the nervous system and the endocrine system. The nervous system sends signals to body organs to keep them working normally. The endocrine system controls the hormones in your body. Hormones act as messengers to the brain and organs to help keep the body working properly. Hormones control many processes in our body, such as growth and digestion. These 2 systems work together to keep your body functioning normally. If cells of the neuroendocrine system start to grow out of control, they can form tumors.

What is advanced PNET?

What are the types of advanced PNET?

Advanced PNET can be functional or nonfunctional.

Functional PNET actively produce hormones that cause disease symptoms
- AFINITOR® (everolimus) Tablets is not for use in people with carcinoid tumors that actively produce hormones

Nonfunctional PNET do not produce enough active hormones to cause disease symptoms but may cause other problems as tumors grow and spread

Persons shown are not actual patients.
AFINITOR may slow the growth and spread of advanced PNET

The benefits and risks of AFINITOR® (everolimus) Tablets have been examined in a large clinical trial studying advanced PNET that has progressed and cannot be treated with surgery. The trial included more than 400 patients with these tumors.

For patients taking AFINITOR, tumor growth was delayed for twice as long compared with patients taking a (placebo) sugar pill (11.0 months for AFINITOR patients compared with 4.6 months for patients on placebo). Approximately 4.8% of patients taking AFINITOR experienced a reduction in tumor size. No patients became tumor-free. It’s important to note that an increase in overall survival has not been shown. AFINITOR is not for use in people with carcinoid tumors that actively produce hormones.

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.

Severe allergic reactions:
Severe allergic reactions can happen in people who take AFINITOR.

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 swelling, 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® (everolimus) Tablets 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 treatment with AFINITOR 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 treatment with AFINITOR and during treatment with AFINITOR.

Important Safety Information (cont)

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, 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

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, 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
How should AFINITOR be taken?

AFINITOR® (everolimus) Tablets is a tablet you take one time each day. Take AFINITOR at the same time every day and in the same way each time, either with food or without food.

AFINITOR tablets should be swallowed whole with a glass of water. Do not take any tablet that is broken or crushed.

You should not drink grapefruit juice or eat grapefruit during your treatment with AFINITOR, as it may make the amount of AFINITOR in your blood increase to a harmful level.

Your health care provider will prescribe the dose of AFINITOR that is right for you. Take AFINITOR exactly as your health care provider tells you to. If needed, your doctor may change your dose of AFINITOR or tell you to temporarily interrupt dosing, if needed.

When you start treatment with AFINITOR, your health care provider may also prescribe a 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.

Use scissors to open the blister pack.

If you take too much AFINITOR, contact your health care provider or go to the nearest hospital emergency department right away. Take the pack of AFINITOR with you.

If you miss a dose of AFINITOR, you may 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 the one that you missed. If you are not sure about what to do, call your health care provider.

How should AFINITOR be taken? (cont)

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.

Important Safety Information (cont)

Tell your health care provider about all of the medicines you take, including prescription and nonprescription medicines, vitamins, and herbal supplements. Using AFINITOR 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
- Seizures
- Bacterial infections
- HIV-AIDS
- Tuberculosis
- 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.
Common Side Effects: Common side effects include mouth ulcers. AFINITOR® (everolimus) Tablets 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-area (abdominal) pain
- Nausea
- Fever
- Cough
- Headache
- Decreased appetite

What are the possible side effects of AFINITOR? (cont)

Important Safety Information (cont)

Other side effects that may occur with AFINITOR:

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

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.

To learn more about AFINITOR, visit www.afinitor.com.
Build strong relationships with your health care team

Your doctors and nurses are here to help you on your journey with advanced PNET. It’s best to speak openly with them about how you feel and your treatment. Here are a few suggestions to help you get the most out of your treatment with AFINITOR® (everolimus) Tablets:

➢ Stick to your treatment plan. Take your medicine as prescribed, and follow all instructions from your doctor, nurse, and pharmacist.
➢ Communicate openly. Get comfortable letting your team know about all your symptoms.

Take an active role in managing your disease

➢ Keep your health care team up to date on prescription and nonprescription medications, allergies, and any changes in your diet.
➢ Keep track of your symptoms as accurately as possible.
➢ If you have any other health conditions, be sure to continue to monitor those as well.
➢ Don’t hesitate to speak up and ask questions about your condition and treatment.

The AFINITOR Patient Support Program: Free access to AFINITOR to help get you started

Novartis Pharmaceuticals Corporation offers the AFINITOR Patient Support Program. If you’re eligible, this program allows you to start receiving a supply of your AFINITOR treatment right away.

14-Day Trial Program: Helping you start on therapy

AFINITOR is available in many different dosages, and we offer a free 14-day trial for each dose strength prescribed by your doctor.

Your free 14-day trial is shipped directly to your home.

Treatment with AFINITOR, even for a short amount of time through the Patient Support Program, may potentially limit a patient’s participation in clinical trials for other therapies. Please talk with your doctor if you have any questions regarding clinical trial options.

How do I get started?

Just talk with your doctor or nurse about the AFINITOR Patient Support Program. The office staff will help you complete the necessary enrollment forms to find out if you are eligible for the program.
Ways we can help

Here are some of the ways we can help:

• Offer support with insurance verification to help you understand your financial responsibilities and where to get your medicine
• Assist with changes in your insurance plan when your coverage changes
• Help you find a pharmacy covered by your plan, and get medication based on your plan guidelines
• Provide Medicare education
• Support for Novartis Oncology medication
• Provide information about other financial assistance that may be available

Novartis Oncology is committed to helping patients who are living with cancer receive the medicines they need. Patient Assistance Now Oncology (PANO) offers quick and easy access to information about our wide range of resources.

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

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

More help on your journey

The following resources can provide additional information about advanced PNET:

National Organization for Rare Disorders — The National Organization for Rare Disorders (NORD) is a unique federation of voluntary health organizations dedicated to helping people with rare “orphan” diseases and assisting the organizations that serve them. NORD is committed to the identification, treatment, and cure of rare disorders through programs of education, advocacy, research, and service.

www.rarediseases.org

Pancreatic Cancer Action Network — The Pancreatic Cancer Action Network is a nationwide network of people; its goal is to advance research, support patients, and create hope for those affected by pancreatic cancer. Its website provides useful tools and information related to pancreatic cancer, treatment options, patient stories, support resources, and more.

www.pancan.org

Pancreatica — The website for this nonprofit organization offers the latest news and information related to clinical trials and other responsible medical care in the treatment of pancreatic cancer. It includes a section dedicated to neuroendocrine tumors.

www.pancreatica.org

These organizations and websites are independently operated by third parties over whom Novartis Pharmaceuticals Corporation has no control. Novartis assumes no responsibility for any information they may provide.
Glossary

Endocrine system
The bodily system that works with the nervous system to carry out the body’s response through the release of hormones.

Functional neuroendocrine tumors
A neuroendocrine tumor that is actively overproducing hormones that may cause symptoms related to hormone activity, such as low blood sugar.

Hormone
A chemical signal that is released into the bloodstream to help direct bodily processes such as metabolism, growth, and reproduction.

Imaging tests
Medical tests that produce pictures or images of the body’s insides and are used to look for cancer, to find out how far it has spread, and to help determine if cancer treatment is working. Some of these tests include X-rays, computed tomography scans, magnetic resonance imaging, and ultrasound.

Mouth ulcers
Sores or open lesions in the mouth that can be caused by some cancer treatments. Tell your health care provider if you have pain, discomfort, or open sores in your mouth. Your health care provider may tell you to use a special mouthwash or mouth gel that does not contain alcohol, hydrogen peroxide, iodine, or thyme.

Nervous system
The bodily system made up of the brain, spinal cord, nerves, and other cells that control your response to a signal from inside or outside the body.

Neuroendocrine tumors
Healthy neuroendocrine cells regulate bodily functions, such as digestion and breathing. When these cells become abnormal, they form tumors, which can adversely affect regular neuroendocrine functioning.

Nonfunctional neuroendocrine tumors
Neuroendocrine tumors do not produce enough active hormones to cause disease symptoms but may cause other problems as tumors grow and spread.

Pancreatic neuroendocrine tumors
Healthy neuroendocrine cells in the pancreas (also known as islet cells) are important regulators of digestive functions, such as the release of insulin. When these cells become abnormal, they form tumors, which can adversely affect regular neuroendocrine functioning.

Placebo
A sugar pill that looks like, and is given in the same manner as, a new drug being tested. A placebo is used in comparison with the test drug to measure its effects.

Pneumonitis
A general term that refers to pain, redness, or swelling of the lung tissues due to irritation or infection. Some chemotherapy drugs and radiation therapy to the chest can cause this reaction. Tell your health care provider right away if you have any of these symptoms: new or worsening cough, shortness of breath, chest pain, difficulty breathing, or wheezing.

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This Is Their Journey

Michael
42 years old

Sarah
51 years old

Jane
59 years old

Earl
65 years old

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