



FYARRO is the first and only FDA-approved treatment for adults with advanced malignant PEComa

PEComa stands for perivascular epithelioid cell tumor

Learn more at FYARRO.com

Made for me

Actor portrayal.

FYARRO is not for everyone. Talk to your doctor to see if FYARRO may be right for you.

Please see full **Prescribing Information** and Important Safety Information on pages 2-3.



Fyarro[®]

sirolimus protein-bound particles
for injectable suspension (albumin-bound)

Indication

FYARRO® is a prescription medicine used to treat adults with malignant perivascular epithelioid cell tumors (PEComa) that have spread to other parts of the body (metastatic) or cannot be removed by surgery (locally advanced, unresectable). It is not known if FYARRO is safe and effective in people with severe liver problems or in children.

Important Safety Information

Do not use FYARRO if you have had a severe allergic reaction to sirolimus or other medications that work similarly to sirolimus (eg, everolimus, temsirolimus), or human albumin.

FYARRO can cause the following serious side effects; depending on the severity, your doctor may decide to decrease your dose or stop treatment with FYARRO:

- **Mouth ulcers and sores** are common during treatment with FYARRO and can be severe. If you develop pain, discomfort, or open sores in your mouth, tell your doctor.
- **Decreased blood cell counts** (red blood cells, platelets, and white blood cells). Your doctor should do blood tests before you start and during treatment with FYARRO.

- **Infections.** FYARRO can make you more susceptible to infections. Tell your doctor right away if you develop a fever, chills, or do not feel well.
- **Low potassium,** which can affect your heart rhythm if severe. Your doctor should do blood tests to check your potassium levels before you start and during treatment with FYARRO.
- **Increased blood sugar levels in blood.** Your doctor should do blood tests before you start and during treatment with FYARRO. Diabetic patients should monitor their blood sugar more frequently.
- **Lung inflammation.** If you develop a persistent cough, chest pain, or shortness of breath, tell your doctor right away.
- **Bleeding,** which can lead to death. If you develop bleeding, tell your doctor right away.
- **Allergic reactions,** which can be severe and life-threatening. Tell your doctor or get medical help right away if you develop swelling of your face, lips, tongue, or throat; a rash, itching, or flushing of your skin; hives; difficulty breathing or swallowing; chest pain; or dizziness.

Important Safety Information (cont'd)

- **Harm to an unborn baby.** Tell your doctor right away if you become pregnant or think you might be pregnant during treatment with FYARRO. Exposure to FYARRO during pregnancy or within 12 weeks before becoming pregnant can cause harm to your baby. If you are able to become pregnant, your doctor should do a pregnancy test before you start treatment with FYARRO. Birth control should be used while receiving FYARRO and for 12 weeks after your last dose of FYARRO. Men with a female partner should use effective birth control during treatment and for 12 weeks after the last dose of FYARRO.
- **Infertility** in woman and men. FYARRO may affect your ability to become pregnant if you are female, or your ability to father a child if you are male.
- **Vaccinations** may be less effective while being treated with FYARRO. In addition, you should not receive a live vaccine or be around people who have recently received a live vaccine during your treatment with FYARRO.

Before taking FYARRO, tell your doctor if you are breast feeding. It is not known if FYARRO could pass into breast milk and harm your baby. You should not breast feed during treatment with FYARRO and for 2 weeks after the last dose. Tell your doctor about all your medical conditions and the medicines you take, including prescription and nonprescription medicines, vitamins, and herbal supplements. Using FYARRO with certain other medicines can cause serious side effects. Tell your doctor before you start taking any new medicine. You should not drink grapefruit juice or eat grapefruit during your treatment with FYARRO. It may make the amount of FYARRO in your blood increase to a harmful level.

The most common side effects with FYARRO include the following: mouth ulcers or sores; feeling weak or tired; rash; infection; nausea; swelling of arms, hands, feet, ankles, face, or other parts of the body; diarrhea; body pain; decreased weight and appetite; cough; vomiting; and altered taste.

These are not all the possible side effects of FYARRO. Tell your doctor if you have any side effect that bothers you or does not go away. 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.

Learn more at FYARRO.com

What is PEComa?

The “PEC” in **PEComa** refers to perivascular epithelioid cells, which are the type of cells that make up the tumor. **Advanced malignant PEComa** is a certain type of cancer known as a soft tissue sarcoma. Sarcomas are a rare type of cancer that forms in the bones and soft tissues, including fat, blood vessels, muscles, and nerves.

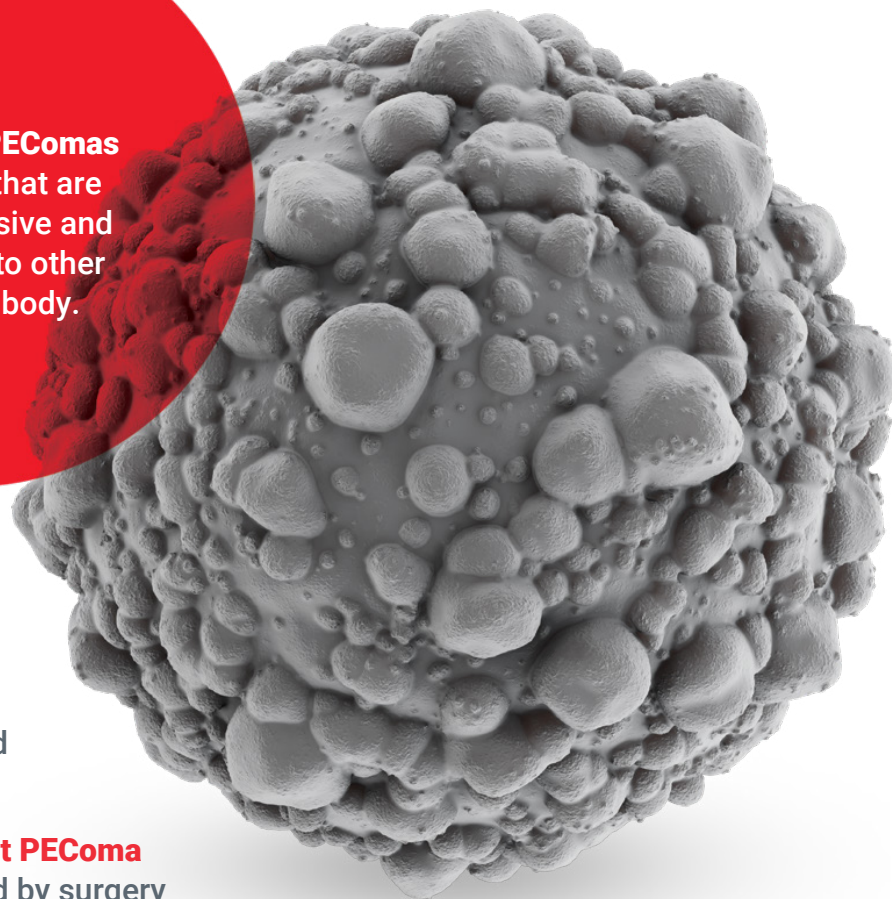


Malignant PEComas are tumors that are very aggressive and can spread to other parts of the body.



If a **malignant PEComa** is found in the early stages, it may be surgically removed with no further treatment.

Locally advanced or metastatic malignant PEComa refers to PEComa that cannot be removed by surgery and/or has spread (metastasized) to other parts of the body.



What is PEComa?

(cont'd)

Malignant PEComa is a rare type of cancer:

There is only about 1 case per year out of every one million people in the world. It can be difficult to diagnose because it often looks like other types of cancer.

Treatment goals

There is no cure for advanced malignant PEComa, but it is treatable. In most cases, the main goal of treatment is to help shrink and control cancer growth as long as possible. If you've been diagnosed with advanced malignant PEComa, you and your doctor will discuss your treatment options and goals.

Until recently, there has been no treatment approved by the FDA for advanced malignant PEComa.



PEComa affects both women and men, but it is somewhat more common in women because it frequently starts in female reproductive organs such as the uterus.

What is FYARRO and how can it help?

FYARRO [FYE-AR'-OH] delivered results in a clinical trial called AMPECT. This means that FYARRO was shown to shrink tumors in some patients. AMPECT studied the effectiveness and safety of FYARRO in 34 adults with advanced malignant PEComa. It is the first and only study completed specifically in adults with advanced malignant PEComa.

Responses that matter:

39% of people (12 out of 31) with malignant PEComa saw their tumors shrink **on FYARRO**

6% of people (2 out of 31) who responded had a complete response (meaning that all signs of cancer disappeared) after 11 months and 34 months on FYARRO*

32% of people (10 out of 31) had a partial response, meaning their tumors shrank but did not completely go away

Responses were fast:

1.4 months was the median amount of time that it took for patients to respond to FYARRO

Responses have lasted:

>3 years 50% of people (6 out of 12) who responded to FYARRO were still responding to treatment after 3 or more years on treatment

People whose tumors responded to FYARRO generally did so in a few months; when responses occurred, the median response lasted >3 years.

*Disappearance of all signs of cancer does not mean the cancer is cured.
AMPECT=Advanced Malignant PEComa Trial; PEComa=perivascular epithelioid cell tumor.

Please see full [Prescribing Information](#) and Important Safety Information on pages 2-3.

 **Fyarro**[®]
sirolimus protein-bound particles
for injectable suspension (albumin-bound)

“FYARRO was made for me.”

Actor portrayal.




FYARRO is the
first and only
FDA-approved
treatment for
advanced malignant
PEComa in adults.

Rare cancer. Approved therapy.

Actor portrayal.

FYARRO is not for everyone. Talk to your doctor to see if FYARRO may be right for you.

Please see full **Prescribing Information** and Important Safety Information on pages 2-3.

 **Fyarro**[®]
sirolimus protein-bound particles
for injectable suspension (albumin-bound)

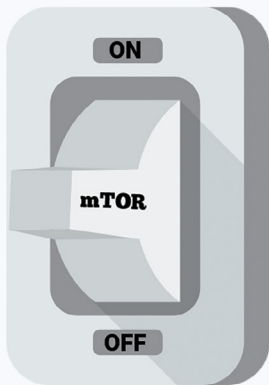
How does FYARRO work?

FYARRO was designed to fight cancer cells

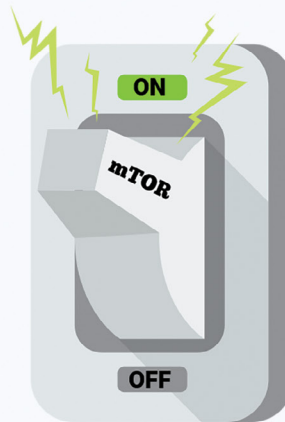
In advanced malignant PEComa, perivascular epithelioid cells grow out of control. FYARRO is thought to block one of the signals in the cancer cells that are causing it to grow out of control, helping to stop cancer from growing or spreading.

FYARRO is not a chemotherapy treatment. It is known as a targeted cancer treatment.

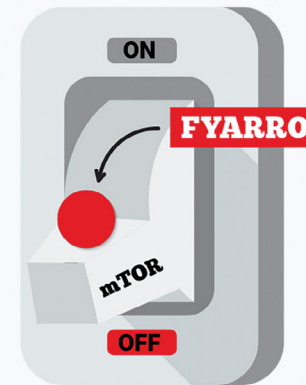
How FYARRO is thought to work



mTOR (short for **mechanistic target of rapamycin**) is a type of **protein** inside cells called a **kinase**. A kinase is like an on/off switch: in healthy cells, mTOR turns growth signals on when they are needed and off when they are not.



For a majority of people with advanced malignant PEComa, the mTOR switch does not function correctly and is **stuck in the "on" position**, allowing the cancer cells to grow out of control.

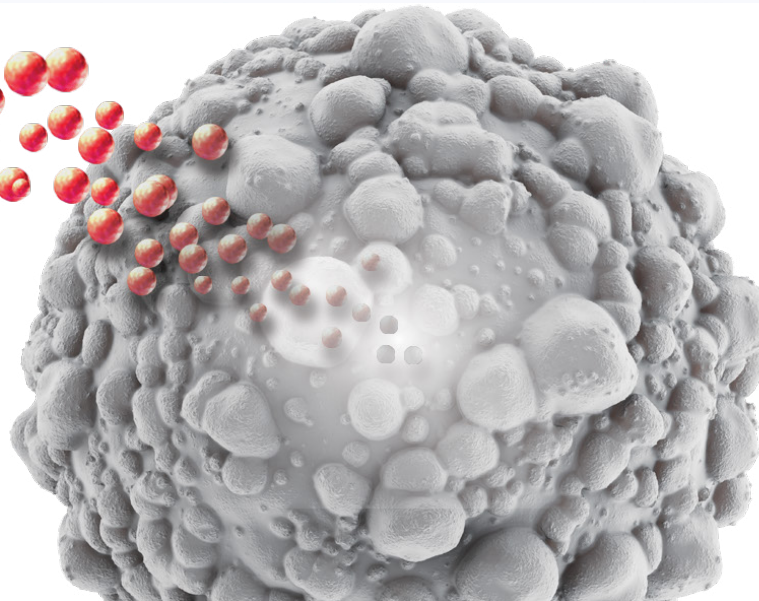


FYARRO is an **mTOR inhibitor**: a **targeted cancer drug** that helps turn the **mTOR switches off** again.



Nanoparticle technology is designed to help FYARRO get more of the drug inside tumors to help turn more mTOR switches off.

These are preclinical data and may not correlate with clinical outcomes.



Please see full **Prescribing Information** and Important Safety Information on pages 2-3.

 **Fyarro**[®]
sirolimus protein-bound particles
for injectable suspension (albumin-bound)

How is FYARRO given?



FYARRO is given as an intravenous (IV) infusion,

which means that the medication is given directly and slowly into the blood through a vein, usually in the arm.



Each infusion of FYARRO takes **30 minutes.**



Each FYARRO treatment cycle is **3 weeks**, which means treatment cycles repeat every 21 days. Doses are given once a week for 2 weeks, on Day 1 and Day 8, followed by 1 week off.



How long will I stay on therapy?

You and your doctor will decide your treatment journey with FYARRO. How long you stay on treatment may be based on factors such as how your tumor has responded to treatment or your body's ability to tolerate treatment. Your doctor may decide to decrease your dose or stop treatment with FYARRO if you experience side effects.

Looking for more answers?

Please see our commonly asked questions on pages 16-17.



**“I’m fighting PEComa.
And I believe
FYARRO is too.”**

Actor portrayal.


Fyarro
sirolimus protein-bound particles
for injectable suspension (albumin-bound)



**Made to fight
malignant PEComa.
Made for me.**

Actor portrayal.

FYARRO is not for everyone. Talk to your doctor to see if FYARRO may be right for you.
Please see full **Prescribing Information** and Important Safety Information on pages 2-3.

 **Fyarro**[®]
sirolimus protein-bound particles
for injectable suspension (albumin-bound)

What should I know before starting FYARRO?

Before you begin treatment with FYARRO, it is important to know about the possible side effects and precautions so that you can be prepared to address them with your doctor if they occur. Contact your doctor immediately if you have any side effects.

During your treatment journey, you may experience the following:



Stomatitis (mouth ulcers and sores) are common during treatment with FYARRO and can be severe. Your doctor may also prescribe an alcohol-free mouthwash to help treat mouth sores



Thrombocytopenia (low blood platelets) and low blood cell counts including **anemia** (low red blood cell count) and **neutropenia** (low white blood cell count) may occur. Your doctor will perform periodic blood tests to check for potential side effects of FYARRO



Infections. FYARRO can make you more susceptible to infections. Tell your doctor right away if you develop a fever, chills, or do not feel well



Hypokalemia (low levels of potassium) and **hyperglycemia** (too much sugar in the blood) are possible during treatment with FYARRO



Inflammation of the lungs. Report any new or worsening respiratory symptoms to your doctor right away, such as trouble breathing



Hemorrhage (severe bleeding). If you experience bleeding, call your doctor right away



Allergic reaction (hypersensitivity). Contact your doctor or seek emergency care for any signs of an allergic reaction including rash, itching, hives, difficulty breathing or swallowing, flushing, chest pain, or dizziness



Pregnancy should be avoided during treatment with FYARRO due to the risk of fetal harm. **Women and men should use contraception** during treatment with FYARRO and for 12 weeks after the last dose. Tell your doctor if you suspect or know you've become pregnant. **Women should not breastfeed** while receiving FYARRO. Fertility issues including difficulty getting pregnant for both females and males may occur



Vaccines may not work as well if you are receiving FYARRO. The use of live vaccines or close contact with other people who have received a live vaccine should be avoided

 **Fyarro**[®]
sirolimus protein-bound particles
for injectable suspension (albumin-bound)

What are the potential side effects of FYARRO?

Be sure to tell a doctor right away about any side effects you may be experiencing with FYARRO. In some cases, side effects may be serious—in the AMPECT study, 41% of patients experienced serious adverse reactions. Serious side effects are those that are life-threatening, require or extend a hospitalization, or result in disability, permanent damage, or a birth defect.

The most common side effects with FYARRO were:

- Stomatitis (mouth ulcers and sores)
- Fatigue (tiredness)
- Rash
- Infection
- Nausea
- Edema (swelling)
- Diarrhea
- Musculoskeletal pain
- Decreased weight
- Decreased appetite
- Cough
- Vomiting
- Dysgeusia (altered taste)

These are not all of the potential side effects of FYARRO. Talk to your doctor for more information and advice.




Good to know

Managing side effects

Some side effects may require your doctor to decrease the dose of FYARRO or skip one or more doses until the side effect goes away. You and your doctor may also choose to stop treatment with FYARRO if you are having side effects and/or are not seeing results with FYARRO.

Actor portrayal.

 **Fyarro**[®]
sirolimus protein-bound particles
for injectable suspension (albumin-bound)

Glossary

A **Albumin** [al-byoo-min] – The main protein found in blood that helps maintain fluid balance in the body.

Anemia [uh-nee-mee-uh] – Having a lower level of red blood cells than normal. This may cause a person to be tired and weak.

C **Chemotherapy treatment** – This is a type of treatment that uses drugs to stop cancer cells from growing. Chemotherapy does this by either killing cells or by preventing them from continuing to divide.

Complete response (CR) – When all signs of cancer disappear. Disappearance of all signs of cancer does not mean the cancer is cured.

D **DNA** – The molecules inside cells that hold genetic information.

Duration of response – The length of time in which the tumor responded to treatment as shown by decreased size or disappearance.

E **Epithelioid** [eh-pih-thee-lee-oyd] – Resembling epithelium, which are cells bound together in a sheet to form the outer layer of skin or lining of body cavities. Epithelioid sarcoma often starts as a slow-growing, firm lump in the body's deep soft tissue or skin. It may be found in areas like the arms, hands, fingers, legs, head, or neck.

H **Hyperglycemia** [hai-per-glai-see-mee-uh] – Having a higher level of blood glucose (a type of sugar in the blood) than normal. While it is more likely to happen in a patient who has diabetes, a patient without diabetes may also experience hyperglycemia.

Hypokalemia [hai-poe-kuh-lee-mee-uh] – Having a lower level of potassium in the body than normal. Potassium helps carry electrical signals in your body. Low levels may cause a person to be weak or have muscle cramps.

I **Intravenous infusion** [in-truh-vee-nus in-fyoo-zhun] – A method of getting fluids, including medication, directly into the body's bloodstream.

Glossary (cont'd)

K **Kinase** [kie-nays] – A special type of protein that speeds up chemical reactions in the body and affects different cell processes. Some kinases are linked to cancer and certain cancer treatments target this protein.

M **Malignant** [muh-lig-nunt] – Refers to cancer cells. Malignant cells can invade nearby tissue and spread to other parts of the body.

Median – The middle number in a group of numbers that are listed from lowest to highest.

Metastatic [meh-tuh-sta-tuhk] – Describes cancer that has spread from where it started (for example, the lungs) to other parts of the body (for example, the brain).

mTOR [em-tor] – Stands for mechanistic target of rapamycin. A protein that supports different cell functions, like cell division and survival. This protein may be more active in certain kinds of cancer. Because of this, a medicine that blocks mTOR may cause cancer cells to die.

mTOR inhibitor [em-tor in-hih-bit-tur] – This type of cancer treatment blocks a protein known as mTOR, which is involved with cell division. It may help prevent cancer cells from growing. It also may stop new blood vessels from forming, which tumors need to grow.

M **Mucositis** [myoo-kuh-sai-tuhs] – Inflammation of the digestive system lining, including the mouth and throat.

Mutation [myoo-tay-shn] – A change in a cell's DNA sequencing.

N **Nanoparticle technology** [na-noe-paar-tuh-kl tek-naa-luh-jee] – A type of technology that uses extremely tiny particles, smaller than 100 nanometers (one-billionth of a meter), to deliver medications to certain parts of the body in a precise way.

O **Overall response rate (ORR)** – An outcome to assess the efficacy of a cancer treatment in clinical trials. ORR is the percent of patients who had tumors shrink by 30% or more, or had all signs of the cancer disappear while receiving treatment.

Glossary (cont'd)

P **Partial response (PR)** – An outcome to assess the efficacy of a cancer treatment in clinical trials. When the tumor size decreases by 30% or more in response to treatment but does not completely go away.

PEComa [pek-o-muh] – Also called perivascular epithelioid cell tumors. These are very rare tumors that start in the soft tissues of the stomach, intestines, lungs, female reproductive organs, and/or urinary organs.

Perivascular [peh-rih-vas-cue-llr] – Describes the space and cells around blood vessels. A perivascular tumor is a type of soft tissue tumor that begins in cells surrounding blood vessels. They can form anywhere in the body.

Pneumonitis [noo-muh-nai-tuhs] – Inflammation in the lungs.

Protein – The molecules in the body made up of building blocks, which are called amino acids. Proteins are critical and are the basis of many parts of the body, including the skin and hair, as well as certain substances like antibodies.

R **Rapamycin** [ra-puh-mie-sin] – This is another name for sirolimus. This is a drug that is now known as sirolimus. It blocks a protein, mTOR, that is involved with cell division.

S **Sarcoma** [saar-koe-muh] – A rare type of cancer that forms in the bone or soft tissues. This can include cartilage, fat, muscles, blood vessels, and other connective tissues.

Sirolimus [sih-rah-lih-mus] – This is a drug that blocks a protein, mTOR, that is involved with cell division. It is also known as rapamycin.

Stomatitis [stoh-muh-ty-tis] – A type of mucositis that occurs when the inside of the mouth has sores or is inflamed.

T **Targeted cancer drug** – A type of cancer treatment that blocks cancer from progressing by targeting specific molecules that help cancer grow and spread.

Thrombocytopenia [thraam-buh-sai-tuh-pee-nee-uh] – Having a lower level of platelets in the blood than normal. This may cause a person to easily bruise or bleed when injured.

Commonly asked questions

Below you will find commonly asked questions that patients may have when starting treatment with FYARRO. Consult with your doctor to make sure that this guidance meets the needs of your individual treatment journey.

1 Where can I find resources to help me live a healthy lifestyle while undergoing treatment?

While there is no set diet or exercise plan for people living with advanced malignant PEComa, there may be things you can do to maintain a healthy lifestyle during your treatment. Talk to your doctor about nutrition and exercise advice. Your treatment center may have a nutritionist on staff whom you can work with.

2 How active can I be during treatment?

Some people may find it helpful to stay active during treatment. Discuss with your doctor how you are feeling so that, together, you can come up with an exercise routine that is best suited for you.

3 Are there any dietary restrictions while on treatment?

Avoid grapefruit and grapefruit juice while taking FYARRO. Talk to your doctor about any herbal supplements that you currently take or are considering taking as they may interact with FYARRO treatment.

4 How many times a month do I receive my treatment?

Each FYARRO treatment cycle is 3 weeks, which means treatment cycles repeat every 21 days. Doses are given once a week for 2 weeks, on Day 1 and Day 8, followed by 1 week off.

5 Does FYARRO impact fertility?

While there are no data on how FYARRO impacts fertility, based on studies in animals and the way FYARRO works, male and female fertility may be affected by treatment with FYARRO. Talk to your doctor if you have specific concerns about fertility.



Commonly asked questions (cont'd)

6 Should I stop taking any medications, vitamins, or herbal supplements during treatment?

Certain medications, vitamins, and herbal supplements may interact with FYARRO treatment. Make sure to tell your doctor about all the medications (prescription and over the counter), vitamins, and herbal supplements that you are currently taking before starting FYARRO and they can let you know which ones you can and cannot take during treatment with FYARRO.

7 Do I have to be concerned about receiving vaccinations during treatment with FYARRO?

You should not receive a live vaccine or be around people who have recently received a live vaccine during your treatment with FYARRO. If you are not sure about the type of vaccine, ask your doctor. Vaccinations may be less effective while being treated with FYARRO.

8 Where can I find patient and caregiver support?

There are organizations created for people living with cancer, including PEComa:

- **Sarcoma Foundation of America** (curesarcoma.org) advocates for sarcoma patients through funding research and raising awareness about this rare cancer
- **Sarcoma Alliance** (sarcomaalliance.org) helps patients and their loved ones connect with others living with sarcoma and find trustworthy information
- **American Cancer Society** (cancer.org) funds and conducts research while also supporting patients by sharing expert advice on living with cancer
- **National Organization for Rare Disorders (NORD)** (rarediseases.org) is an advocacy organization for people with rare diseases as well as the organizations that support them. With 300 organization members, NORD is committed to serving patients and furthering research in rare diseases

You can also visit FYARRO.com to learn more about FYARRO and advanced malignant PEComa.

9 Where can I find more information on patient support programs?

AadiAssist provides support services for patients taking FYARRO. See page 18 of this brochure or visit AadiAssist.com for more information on access and reimbursement support.



Patient support with AadiAssist



We have resources to help you access FYARRO.

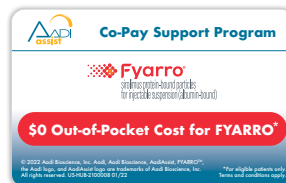
**Insurance education
and support**



Contact us if you have questions about your insurance for FYARRO.

Call **1-855-AADIHUB** (1-855-223-4482)
Monday-Friday, 8 AM-8 PM ET

**Financial support
for patients***



We have a variety of patient support programs that may help with issues like coverage delays, co-pay assistance, and inadequate insurance coverage.

*Terms and conditions apply.

**We're here to
support you**



Resources to help you access FYARRO.

Learn more at [AadiAssist.com](https://www.aadiassist.com)

Notes



At Aadi Bioscience, our mission is to improve the lives of people with mTOR-driven diseases. We believe success depends on addressing current treatment limitations.

For more information, please visit [Aadibio.com](https://www.aadibio.com).

Please see full **Prescribing Information** and Important Safety Information on pages 2-3.

FYARRO® is a registered trademark of Aadi Bioscience, Inc. © 2023 Aadi Bioscience, Inc. All rights reserved. US-FYA-2300034 4/23

 **Fyarro**®
sirolimus protein-bound particles
for injectable suspension (albumin-bound)