

National Comprehensive Cancer
Network® (NCCN®) preferred

The **only** preferred regimen for malignant PEComa
(locally advanced unresectable or metastatic disease)^{1*}

FYARRO is the
FIRST AND ONLY
treatment that can...

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

G O D E E P

FOR DURABLE RESPONSES

FYARRO TREATMENT GUIDE

Taking the fight to malignant
PEComa with nanoparticle technology,
FYARRO penetrates tumors for
powerful responses that last

INDICATION

FYARRO® is an mTOR inhibitor indicated for the treatment of adult patients with locally advanced unresectable or metastatic malignant perivascular epithelioid cell tumor (PEComa).

*All NCCN recommendations for malignant PEComa are category 2A. * NCCN makes no warranties of any kind whatsoever regarding their content, use, or application, and disclaims any responsibility for their application or use in any way.
PEComa=perivascular epithelioid cell tumor.

Please see [full Prescribing Information](#) and [Important Safety Information](#).



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Contraindications

- History of severe hypersensitivity to sirolimus, other rapamycin derivatives, or albumin.

Warnings and Precautions

FYARRO can cause serious adverse reactions. Withhold, resume at reduced dose, or permanently discontinue FYARRO based on severity (See Dosage and Administration of full Prescribing Information).

- **Stomatitis:** Stomatitis, including mouth ulcers and oral mucositis, occurred in 79% of patients, including 18% Grade 3.
- **Myelosuppression:** FYARRO can cause myelosuppression including anemia, thrombocytopenia and neutropenia. Anemia occurred in 68% of patients; 6% were Grade 3. Thrombocytopenia and neutropenia occurred in 35% of patients each. Obtain blood counts at baseline and every 2 months for the first year of treatment and every 3 months thereafter, or more frequently if clinically indicated.
- **Infections:** FYARRO can cause infections. Infections such as urinary tract infections (UTI), upper respiratory tract infections and sinusitis occurred in 59% of patients. Grade 3 infections occurred in 12% of patients, including a single case each of a UTI, pneumonia, skin, and abdominal infections. Monitor for signs and symptoms of infection.
- **Hypokalemia:** FYARRO can cause hypokalemia. Hypokalemia occurred in 44% of patients, including 12% Grade 3 events. Monitor serum potassium prior to starting FYARRO and supplement potassium as medically indicated.

- **Hyperglycemia:** FYARRO can cause hyperglycemia. Hyperglycemia occurred in 12% of patients, all of which were Grade 3 events. Monitor fasting serum glucose prior to starting FYARRO. During treatment, monitor serum glucose every 3 months in non-diabetic patients, or as clinically indicated. Monitor more frequently in diabetic patients.
- **Interstitial Lung Disease (ILD)/Non-Infectious Pneumonitis:** FYARRO can cause ILD/non-infectious pneumonitis, which occurred in 18% of patients, all Grades 1 or 2. Monitor for new or worsening respiratory symptoms or radiological changes.
- **Hemorrhage:** FYARRO can cause serious and sometimes fatal hemorrhage. Hemorrhage occurred in 24% of patients, including Grade 3 and Grade 5 events in 2.9% of patients each. Monitor for signs and symptoms.
- **Hypersensitivity Reactions:** FYARRO can cause hypersensitivity reactions, including anaphylaxis. Anaphylaxis, angioedema, exfoliative dermatitis and hypersensitivity vasculitis have been observed with use of oral sirolimus. Monitor for hypersensitivity during and following each FYARRO infusion. Monitor for at least 2 hours following completion of the first infusion and as clinically indicated for each subsequent infusion. Reduce the rate, interrupt infusion, or permanently discontinue based on severity.
- **Embryo-Fetal Toxicity:** Can cause fetal harm. Advise patients of the potential hazard to the fetus and to use effective contraception while using FYARRO and for 12 weeks after the last dose.
- **Male Infertility:** Azoospermia or oligospermia may occur.
- **Immunizations:** Avoid live vaccines.

Adverse Reactions

- The most common ($\geq 30\%$) adverse reactions were stomatitis, fatigue, rash, infection, nausea, edema, diarrhea, musculoskeletal pain, decreased weight, decreased appetite, cough, vomiting, and dysgeusia.
- The most common ($\geq 6\%$) Grade 3 to 4 laboratory abnormalities were decreased lymphocytes, increased glucose, decreased potassium, decreased phosphate, decreased hemoglobin, and increased lipase.

Drug Interactions

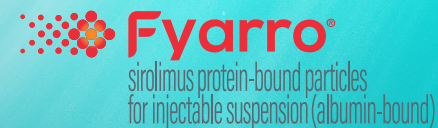
- **Strong CYP3A4 and/or P-gp Inhibitors or Inducers:** Avoid concomitant use.
- **Moderate or Weak CYP3A4 Inhibitors:** Reduce FYARRO dose.

Use in Specific Populations

- **Hepatic Impairment:** Reduce the dose of FYARRO in patients with mild or moderate hepatic impairment. Avoid use in patients with severe hepatic impairment.
- **Lactation:** Advise not to breastfeed.
- **Females and Males of Reproductive Potential:** May impair fertility in females and males.

AMPECT: THE FIRST AND ONLY PROSPECTIVE STUDY COMPLETED IN ADVANCED MALIGNANT PEComa²

MULTICENTER, SINGLE-ARM, OPEN-LABEL, PHASE 2 REGISTRATIONAL STUDY EVALUATING FYARRO IN 34 PATIENTS (SAFETY POPULATION)²



ADULT PATIENTS
WITH CONFIRMED
METASTATIC OR
LOCALLY ADVANCED
MALIGNANT PEComa²

FYARRO 100 mg/m²
ON DAYS 1 AND 8 OF
A 21-DAY CYCLE^{2*}

PATIENTS WERE
TREATED UNTIL
DISEASE PROGRESSION
OR UNACCEPTABLE
TOXICITY²

PRIMARY ENDPOINT²

- Overall response rate (ORR by RECIST v1.1 criteria) assessed by independent radiology review

SECONDARY ENDPOINTS³

- Duration of response (DOR)
- Progression-free survival (PFS)
- Overall survival (OS)

EXPLORATORY ENDPOINTS²

- Post hoc analysis of disease control rate (DCR; defined as the percentage of patients with a confirmed response or with SD of ≥12 weeks' duration)
- Tumor biomarker analyses

Primary analysis[†] at 6 months after the last patient initiated therapy²

Second analysis performed 2 years after the last patient initiated therapy (1.5 years following primary analysis)²

Study-end analysis 3-year follow-up after the primary analysis (3.5 years after last patient initiated therapy)³

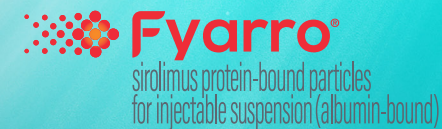
*A maximum of 2 dose reductions by 25% each (to 75 and then 56 mg/m²) were permitted for toxicity.²

[†]The primary analysis was preplanned to occur when the last enrolled patient had been treated for 6 months.²

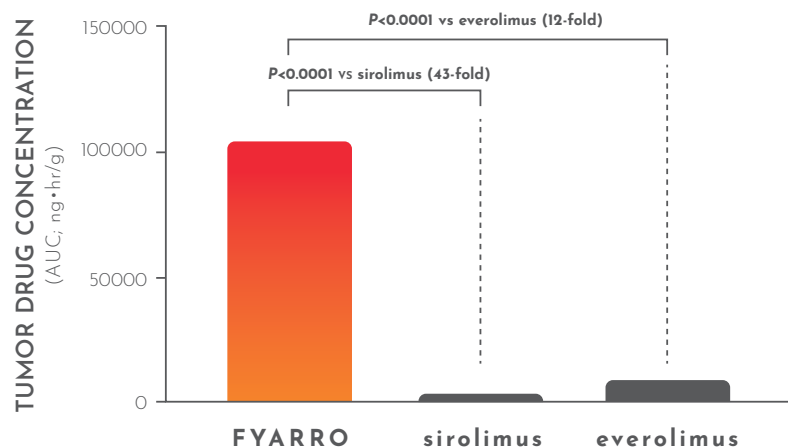
AMPECT=Advanced Malignant PEComa Trial; PEComa=perivascular epithelioid cell tumor; RECIST=Response Evaluation Criteria in Solid Tumors; SD=stable disease.

TARGETED THERAPY THAT GOES DEEP

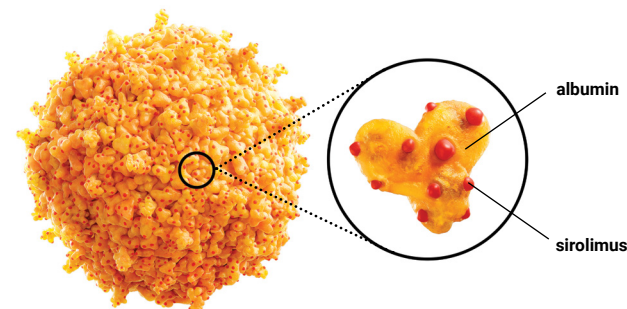
ONLY FYARRO USES PROVEN NANOPARTICLE ALBUMIN-BOUND (*nab*)
TECHNOLOGY ENGINEERED TO ACHIEVE POTENT, TARGETED mTOR SUPPRESSION^{4,5}



SIGNIFICANTLY HIGHER TUMOR ACCUMULATION VS ORAL mTOR INHIBITORS IN VIVO^{4*}



From a study of UMC3 human bladder cancer xenografts in athymic nude mice receiving equivalent weekly doses (15 mg/kg/week) of IV FYARRO (7.5 mg/kg, 2x/week) or oral sirolimus or everolimus (3 mg/kg, 5x/week).⁴ Adapted from Hou et al. Aadi Bioscience, Inc. 2019.



FYARRO is the first and only mTOR inhibitor using *nab* technology engineered to deliver high levels of drug to tumors^{4,5}

- Nonclinical studies demonstrated significant pharmacodynamic improvement over oral mTOR inhibitors, including^{4,6*}:
 - ▶ Enhanced bioavailability
 - ▶ Higher tumor drug concentrations
 - ▶ Increased mTOR target suppression
 - ▶ Stronger antitumor activity

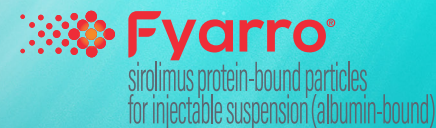
***Nonclinical data may not correlate with clinical outcomes.**

AUC=area under the curve; IV=intravenous; mTOR=mechanistic target of rapamycin; UMC3=University of Michigan-Urothelial Carcinoma-3.

Please see [full Prescribing Information](#) and [Important Safety Information](#).

RESPONSES THAT LAST

FYARRO DELIVERED RAPID AND DURABLE CLINICAL EFFICACY
AGAINST ADVANCED MALIGNANT PEComa



CLINICAL OUTCOMES AT STUDY-END ANALYSIS (N=31)³

PRIMARY ENDPOINT

OVERALL RESPONSE RATE (ORR)

39% per independent review using RECIST v1.1 (12/31 [efficacy population]; 95% CI: 22%, 58%)³

RAPID RESPONSE

1.4 MONTHS median time to response (95% CI: 1.3, 2.8 months)²

DURABLE RESPONSE

>3 YEARS 50% of patients had a DOR of 39.7+ months (95% CI: 6.5 months to not reached)³



DISEASE CONTROL RATE **71%** of patients with a confirmed response or with SD of ≥12 weeks' duration (95% CI: 52%, 85.8%)^{3*}



HALF OF RESPONDERS WERE STILL RESPONDING AFTER 3 YEARS³

***Disease control rate was a post hoc exploratory endpoint and was not prespecified. Therefore it should be interpreted with caution.^{3,7}**

CR=complete response; DOR=duration of response; PD=progressive disease; PEComa=perivascular epithelioid cell tumor; PR=partial response; RECIST=Response Evaluation Criteria in Solid Tumors; SD=stable disease.

Please see [full Prescribing Information](#) and [Important Safety Information](#).

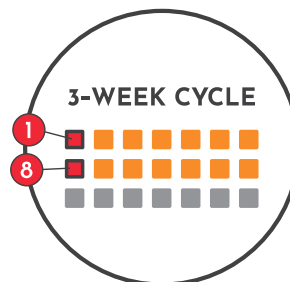
DOSING AND ADMINISTRATION



IV INFUSION



30 MINUTES



DAYS 1 & 8 OF EACH
21-DAY CYCLE

- Recommended dose of FYARRO is 100 mg/m² administered as an IV infusion over 30 minutes on days 1 and 8 of each 21-day cycle
 - ▶ Recommended dose until disease progression or unacceptable toxicity
- No known dose adjustment necessary based on age, gender, race, or impaired renal function
- FYARRO can cause serious adverse reactions. Withhold, resume at reduced dose, or permanently discontinue FYARRO based on severity (see Dosage and Administration within [full Prescribing Information](#))

IV=intravenous.



Reduce the dosage of FYARRO to 56 mg/m² when used concomitantly with a moderate or weak cytochrome P-450 3A4 (CYP3A4) inhibitor. Avoid concomitant use with drugs that are strong CYP3A4 and/or P-glycoprotein (P-gp) inhibitors and inducers and with grapefruit and grapefruit juice.



Use in patients with severe hepatic impairment is not recommended. Dose reductions to 75 mg/m² and 56 mg/m² are recommended in patients with mild and moderate hepatic impairment, respectively.

IN AMPECT, MOST TREATMENT-RELATED ADVERSE REACTIONS WERE GRADE 1 OR 2²

- 65% of patients required no dose reduction; 35% of patients required a dose reduction due to an adverse reaction
 - ▶ The most common reasons for dose reductions were stomatitis and pneumonitis
- 65% of patients had a dose interruption due to an adverse reaction
- Three patients (9%) discontinued treatment due to an adverse reaction (pneumonitis, anemia, and noninfective cystitis)

RECOMMENDED DOSE REDUCTIONS IN RESPONSE TO ADVERSE REACTIONS	
STARTING DOSE	100 mg/m ²
RECOMMENDED DOSE REDUCTIONS	
FIRST REDUCTION	75 mg/m ² (25% reduction from 100 mg/m ²)
SECOND REDUCTION	56 mg/m ² (25% reduction from 75 mg/m ²)
THIRD REDUCTION*	45 mg/m ² (20% reduction from 56 mg/m ²)

*Permanently discontinue FYARRO in patients who are unable to tolerate FYARRO after 3 dose reductions.











In the AMPECT study, stomatitis was the most common adverse reaction with FYARRO.

Supportive care measures, including use of steroid mouthwash and/or other oral treatments were permitted during the study.⁸

AMPECT=Advanced Malignant PEComa Trial.

Please see [full Prescribing Information](#) and [Important Safety Information](#).

ADVERSE REACTION MANAGEMENT

ADVERSE REACTION	SEVERITY*	MODIFICATION	ADVERSE REACTION	SEVERITY*	MODIFICATION
 STOMATITIS	Grade 2 or 3	<ul style="list-style-type: none"> Withhold FYARRO until Grade ≤ 1 Restart at the same dose for first occurrence If recurs, restart at reduced dose level 	 HYPOKALEMIA	Grade 2	<ul style="list-style-type: none"> Withhold FYARRO until Grade ≤ 1 Restart at the same dose level If recurs, restart at reduced dose level
	Grade 4	<ul style="list-style-type: none"> Permanently discontinue FYARRO 		Grade ≥ 3	<ul style="list-style-type: none"> Withhold FYARRO until Grade ≤ 1 Restart at reduced dose level If recurs, permanently discontinue FYARRO
 ANEMIA	Grade 2	<ul style="list-style-type: none"> Withhold FYARRO until Hb ≥ 8 g/dL Restart at the same dose level 	 HYPERGLYCEMIA	Grade ≥ 3	<ul style="list-style-type: none"> Withhold FYARRO until Grade ≤ 2 Restart at reduced dose level
	Grade ≥ 3	<ul style="list-style-type: none"> Withhold FYARRO until Hb ≥ 8 g/dL Restart at the same dose level If recurs, resume at reduced dose level 			
 THROMBOCYTOPENIA	Grade 2	<ul style="list-style-type: none"> Withhold FYARRO until platelet count $> 100 \times 10^9/L$ Restart at the same dose level 	 INTERSTITIAL LUNG DISEASE/ NONINFECTIOUS PNEUMONITIS	Grade 2	<ul style="list-style-type: none"> Withhold FYARRO for up to 3 weeks until Grade ≤ 1 Restart at reduced dose level If not resolved to Grade ≤ 1 within 3 weeks, permanently discontinue FYARRO If recurs, permanently discontinue FYARRO
	Grade ≥ 3	<ul style="list-style-type: none"> Withhold FYARRO until platelet count $> 100 \times 10^9/L$ Restart at reduced dose level 		Grade ≥ 3	<ul style="list-style-type: none"> Permanently discontinue FYARRO
 NEUTROPENIA	Grade 2 or 3	<ul style="list-style-type: none"> Withhold FYARRO until absolute neutrophil count $\geq 1.5 \times 10^9/L$ Restart at the same dose level 	 HEMORRHAGE	Grade 2 or 3	<ul style="list-style-type: none"> Withhold FYARRO until Grade ≤ 1 Resume at reduced dose If recurs, permanently discontinue FYARRO
	Grade 4	<ul style="list-style-type: none"> Withhold FYARRO until absolute neutrophil count $\geq 1.5 \times 10^9/L$ Restart at reduced dose level 		Grade 4	<ul style="list-style-type: none"> Permanently discontinue FYARRO
 INFECTIONS	Grade 3	<ul style="list-style-type: none"> Withhold FYARRO until resolved Restart at reduced dose level If recurs, permanently discontinue FYARRO 	 OTHER ADVERSE REACTIONS	Grade 3	<ul style="list-style-type: none"> Withhold FYARRO until Grade ≤ 1 Restart at the same dose level If recurs, restart at reduced dose level
	Grade 4	<ul style="list-style-type: none"> Withhold FYARRO until resolved Restart at reduced dose level or permanently discontinue FYARRO 		Grade 4	<ul style="list-style-type: none"> Permanently discontinue FYARRO

*Severity based on National Cancer Institute Common Terminology Criteria for Adverse Events Version 4.03.

DRUG INTERACTION RECOMMENDATIONS

- No formal drug interaction studies have been conducted
- Sirolimus is known to be a substrate for both CYP3A4 and P-gp; inducers of CYP3A4 and P-gp may decrease sirolimus concentrations whereas inhibitors of CYP3A4 and P-gp may increase sirolimus concentrations
- Avoid concomitant use of FYARRO with grapefruit and grapefruit juice

DRUG INTERACTION	Strong inducers or inhibitors of CYP3A4 (including grapefruit and grapefruit juice) and/or P-gp	Moderate or weak inhibitor of CYP3A4 and/or P-gp	Moderate or weak inducers of CYP3A4
RECOMMENDATION	Concomitant use should be avoided	FYARRO dose reduction to 56 mg/m ² per dose should be considered	May result in decreased efficacy of FYARRO

PREPARATION AND ADMINISTRATION

FYARRO IS SUPPLIED AS A STERILE LYOPHILIZED POWDER FOR RECONSTITUTION BEFORE USE

1

Aseptically, reconstitute each vial by injecting 20 mL of 0.9% Sodium Chloride Injection, USP.

2



Slowly inject the 20 mL of 0.9% Sodium Chloride Injection, USP, over a minimum of 1 minute, using the sterile syringe to direct the solution flow onto the INSIDE WALL OF THE VIAL.

3

DO NOT INJECT the 0.9% Sodium Chloride Injection, USP, directly onto the lyophilized powder, which has a cake-like appearance, as this will result in foaming.

4



Once the injection is complete, allow the vial to sit for a minimum of 5 minutes to ensure proper wetting of the lyophilized powder.

5



Gently swirl and/or invert the vial slowly for at least 2 minutes until complete dissolution of any powder occurs. Avoid shaking the vial to prevent the generation of foam.

FYARRO IS SUPPLIED AS A STERILE LYOPHILIZED POWDER FOR RECONSTITUTION BEFORE USE

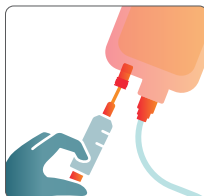
6

If foaming or clumping occurs, let suspension stand for at least 15 minutes until foam subsides. If foaming or clumping is present after one hour, do not use the reconstituted suspension.

- Each mL of the reconstituted formulation will contain 5 mg sirolimus
- The reconstituted suspension should be milky and homogenous without visible particulates. If particulates or settling are visible, the vial should be gently inverted again to ensure complete resuspension prior to use. Discard the reconstituted suspension if precipitates are observed. Discard any unused portion

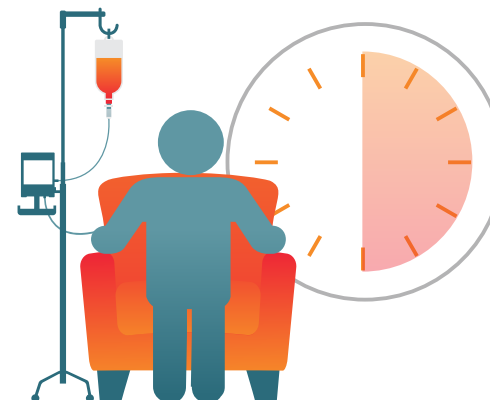
7

Transfer the volume of FYARRO required for the calculated dose into an empty sterile PVC or polyolefin infusion bag for administration without further dilution.



- The use of medical devices containing silicone oil as a lubricant (eg, syringes and intravenous bags) to reconstitute and administer FYARRO may result in the formation of proteinaceous strands
- Visually inspect reconstituted FYARRO suspension in the infusion bag prior to administration. Discard reconstituted suspension if particulate matter, proteinaceous strands, or discoloration are observed

ADMINISTRATION



Administer the reconstituted FYARRO suspension intravenously over 30 minutes.

FYARRO IS A WHITE TO YELLOW, STERILE LYOPHILIZED POWDER.
EACH CARTON CONTAINS 1 SINGLE-DOSE VIAL WITH 100 MG OF SIROLIMUS.



Store the vials in the original cartons at 2 to 8 °C (36 to 46 °F)



Keep in the original package to protect from light



FYARRO is a hazardous drug. Follow applicable special handling and disposal procedures



ENROLL YOUR PATIENTS

Visit AadiAssist.com to download the enrollment form



SUPPORT SERVICES

Benefits investigation (BI)

AadiAssist will confirm a patient's coverage with their insurance company.

Prior authorization (PA) and appeals support

By calling us, we can help streamline the insurance process.

Insurance education

Patients can call us for help regarding insurance coverage for FYARRO.



CONTACT US

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

*Additional terms and conditions apply.



FINANCIAL SUPPORT*

Co-Pay Support Program

Patients with commercial or private insurance may be eligible to receive co-payment assistance to help with out-of-pocket costs for FYARRO up to a maximum dollar amount of \$25,000 annually.



Patient Assistance Program (PAP)

Patients who are uninsured or underinsured may be eligible to obtain access to FYARRO at no cost through the AadiAssist PAP. To qualify for assistance, patients must meet certain eligibility criteria, as detailed on the PAP enrollment form. A case manager will contact your office with determination of patient's eligibility.

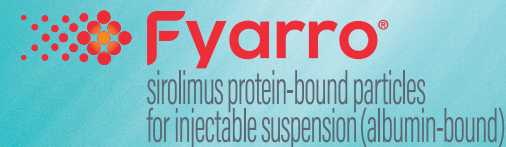
CODE	DESCRIPTION
NATIONAL DRUG CODE (NDC)	Payer requirements regarding the use of a 10-digit or 11-digit NDC may vary. Both formats are listed here for your reference
10-DIGIT	80803-153-50
11-DIGIT	80803-0153-50
CURRENT PROCEDURAL TERMINOLOGY (CPT)	
96413	Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug
96415	Chemotherapy administration, intravenous infusion technique; each additional hour (list separately in addition to code for primary procedure)
HEALTHCARE COMMON PROCEDURE CODING SYSTEM (HCPCS)	HCPCS coding requirements will vary by payer, setting of care, and date of service. Please verify patient-specific insurance benefits to confirm specific coding and billing guidelines for FYARRO
J-9331	Injection, Sirolimus protein-bound particles, 1 mg

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1. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Soft Tissue Sarcoma V.2.2022. ©National Comprehensive Cancer Network, Inc. 2022. All rights reserved. Accessed January 24, 2023. To view the most recent and complete version of the guidelines, go to NCCN.org.
2. Wagner AJ, Ravi V, Riedel RF, et al. *nab*-Sirolimus for patients with malignant perivascular epithelioid cell tumors. *J Clin Oncol*. 2021;39(33):3660-3670. doi:10.1200/JCO.21.01728
3. Wagner AJ, Ravi V, Riedel RF, et al. Study-end analysis from AMPECT, an open-label, phase 2 registration trial of patients with advanced malignant PEComa treated with *nab*-sirolimus, showing durability of response and long-term safety. Poster presented at: Connective Tissue Oncology Society Meeting; Vancouver, BC, Canada; November 16-19, 2022.
4. Hou S, Schmid AN, Desai N. ABI-009 (*nab*-sirolimus) improves tumor accumulation and antitumor activity over oral mTOR inhibitors. Poster presented at: AACR Annual Meeting; Atlanta, GA; March 29-April 3, 2019.
5. Gonzalez-Angulo AM, Meric-Bernstam F, Chawla S, et al. Weekly *nab*-rapamycin in patients with advanced nonhematologic malignancies: final results of a phase I trial. *Clin Cancer Res*. 2013;19(19):5474-5484. doi:10.1158/1078-0432.CCR-12-3110
6. Wagner AJ, Ravi V, Riedel RF, et al. Final analysis from AMPECT, an open-label phase 2 registration trial of *nab*-sirolimus for patients with advanced malignant perivascular epithelioid cell tumors (PEComa). Abstract presented at: CTOS Virtual Annual Meeting; November 12, 2021.
7. Data on file. Aadi Bioscience, Inc.; 2021.
8. Ganjoo KN, Dickson MA, Ravi V, et al. Management of adverse events in the AMPECT trial of *nab*-sirolimus for the treatment of advanced malignant perivascular epithelioid cell neoplasm (PEComa). Poster presented at: Connective Tissue Oncology Society Annual Meeting; November 16-19, 2022; Vancouver, BC, Canada.

3-YEAR DATA, DURABLE RESPONSES

ACHIEVED DURABLE RESPONSES IN THE FIRST AND ONLY PROSPECTIVE STUDY COMPLETED IN ADVANCED MALIGNANT PEComa³



PRIMARY ENDPOINT³

DEMONSTRATED
RESPONSE

39% ORR

per independent review using
RECIST v1.1 (12/31 [efficacy
population]; 95% CI: 22%, 58%)



MANAGEABLE SAFETY PROFILE

- The most common adverse reactions ($\geq 30\%$) were stomatitis, fatigue, rash, infection, nausea, edema, diarrhea, musculoskeletal pain, decreased weight, decreased appetite, cough, vomiting, and dysgeusia
- Most adverse reactions were mild or moderate in severity (Grade 1 or 2) and manageable²
- Serious adverse reactions occurred in 14 (41%) patients who received FYARRO
- Three patients (9%) discontinued therapy due to an adverse reaction

SECONDARY ENDPOINTS AT STUDY-END ANALYSIS³

DURABLE
RESPONSE

Median DOR

>3 years

39.7 months
(95% CI: 6.5 months
to not reached)

PROGRESSION-FREE
SURVIVAL (PFS)*

Median PFS

~1 year

10.6 months
(95% CI: 5.5, 41.2 months)

OVERALL
SURVIVAL (OS)*

Median OS

>4 years

53.1 months
(95% CI: 22.2 months
to not reached)

***Survival data should be interpreted with caution given the single-arm study design.**

DOR=duration of response; ORR=overall response rate; PEComa=perivascular epithelioid cell tumor; RECIST=Response Evaluation Criteria in Solid Tumors.

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Please see [full Prescribing Information](#) and [Important Safety Information](#).

