Responses That Last

FYARRO delivered rapid and durable clinical efficacy against advanced malignant PEComa

AMPECT Study
Efficacy-late
Overall Response
Durable Response
Learn about dosing and administration

CLINICAL OUTCOMES AT STUDY-END ANALYSIS (N=31)[1]

PRIMARY ENDPOINT
OVERALL RESPONSE RATE (ORR)

39%

per independent review using RECIST v1.1 (12/31 [efficacy population]; 95% CI: 22%, 59%)[1]

RAPID RESPONSE

1.4 months

median time to response (95% CI: 1.1, 2.8 months)[1]

DURABLE RESPONSE

>3 years

50% of patients had a DOR of 39.7+ months (95% CI: 15 months is not reached)[1]

DISEASE CONTROL RATE **71%** of patients with a confirmed response or with SD of ≥12 weeks' duration (95% CI: 52%, 85.8%)[1,2]

HALF OF RESPONDERS WERE STILL RESPONDING AFTER 3 YEARS[1]

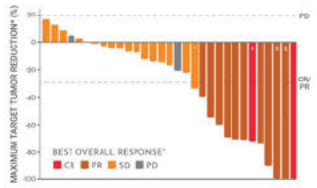
[1]Disease control rate was a post hoc exploratory endpoint and was not prespecified. Therefore it should be interpreted with caution.[1,2]

AMPECT=Advanced Malignant PEComa Trial; 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.

In AMPECT, 2 patients experienced complete responses after 11 months and 34 months of treatment[1,4]

TARGET LESION CHANGES AT STUDY-END ANALYSIS (N=31)[1,5]

RECIST v1.1 criteria, per independent review



*Target tumor reduction may not match Best Overall Response Assessment, which also takes into consideration nontarget lesions and the observations of new lesions as per RECIST v1.1 (SD and PD could be due to the natural course of the disease and not due to treatment).[1]

†One patient had an unconfirmed PR and thus best response is SD as per RECIST v1.1 (confirmation of response requirement).[1,2]

‡One patient with overall CR had a measurable lymph node as target tumor, but <10 mm.[1]

§Two patients with 0% of target tumor reduction had PRs as best response because of unresolved nontarget lesions.[1]

Image was adapted from Wagner et al. Target lesion changes per multinational status–final analysis figure. CTOS; 2022.

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FYARRO goes the distance for patients with PEComa

SECONDARY ENDPOINTS (KAPLAN-MEIER ESTIMATES)[1]

MEDIAN PFS*

MEDIAN OS*

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

nab-sirolimus=albumin-bound; OS=overall survival; PEComa=perivascular epithelioid cell tumor; PFS=progression-free survival.

References: 1. 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 19-19, 2022. 2. Wagner AJ, Ravi V, Riedel RF, et al. nab-Sirolimus for patients with malignant perivascular epithelioid cell tumors. J Clin Oncol. 2021;39(30):3360-3670. doi:10.1200/JCO.21.01709 3. Data in file. AadiBioscience, Inc.; 2021. 4. 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 10, 2021. 5. Eisenhauer EA, Therasse P, Bogaerts J, et al. New response evaluation criteria in solid tumours: revised RECIST guideline (version 1.1). Eur J Cancer. 2009;45:228-247. doi:10.1016/j.ejca.2008.10.026

Mass. Safety

Important Safety Information

Contraindication

- 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 71% of patients, including 16% Grade 3.
- **Myelosuppression:** FYARRO can cause myelosuppression including anemia, thrombocytopenia and neutropenia. Anemia occurred in 48% 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 39% 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 10% 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 (≥20%) adverse reactions were stomatitis, fatigue, rash, infection, nausea, edema, diarrhea, musculoskeletal pain, decreased weight, decreased appetite, cough, vomiting, and dyspnoea.
- The most common (≥4%) 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.

Please see **full Prescribing Information**

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).