How important is it to get her flaring signs and symptoms under control?

Not an actual patient

Patient with newly flaring lupus nephritis

Julia T., 29-year-old patient with lupus nephritis

- Julia was diagnosed with lupus nephritis 2 years ago and achieved a partial renal response after 12 months of treatment with MMF + steroids
- At her most recent follow-up, lab results showed significantly elevated UPCR relative to her previous visit
- Her physician wants to help ensure that the current flare of lupus nephritis is controlled as quickly as possible

MMF=mycophenolate mofetil; UPCR=urine protein/creatinine ratio.

Indications

LUPKYNIS is indicated in combination with a background immunosuppressive therapy regimen for the treatment of adult patients with active lupus nephritis (LN). *Limitations of Use*: Safety and efficacy of LUPKYNIS have not been established in combination with cyclophosphamide. Use of LUPKYNIS is not recommended in this situation.

Important Safety Information

BOXED WARNINGS: MALIGNANCIES AND SERIOUS INFECTIONS – Increased risk for developing malignancies and serious infections with LUPKYNIS or other immunosuppressants that may lead to hospitalization or death.

Please see additional Important Safety Information and Prescribing Information including Boxed Warning and Medication Guide for LUPKYNIS.

Lupkynis™ (voclosporin) capsules 7.9 mg

Clinical history

Julia T., 29-year-old patient with lupus nephritis

Diagnosed with lupus nephritis 2 years ago

- UPCR 2.3 mg/mg at diagnosis
- Treated with MMF (2.5 g/day) and steroids for 12 months, achieved a partial response (50% reduction in UPCR)

Current biopsy findings

- ISN Class IV
- Diffuse proliferative lupus nephritis affecting 70% of glomeruli
- Subendothelial and mesangial immune deposition

SLE history

- Diagnosed with SLE 3.5 years prior

Current medications

- Hydroxychloroquine (200 mg BID)
- Prednisone (5 mg/day)
- MMF (1.5 g/day)
- Oral birth control
- Angiotensin II receptor blocker

Laboratory findings and vitals

	At lupus nephritis diagnosis (2 years prior)	6 months prior	Present day
UPCR (mg/mg)	2.3	1.0	3.6
Serum albumin (g/dL)	3.0	3.6	2.8
Urine microscopy	5 RBC/HPF	No active sediment	8 RBC/HPF
eGFR (mL/min/1.73 m²)	88	90	80
Serum creatinine (mg/dL)	0.9	0.9	0.9
C3 (mg/dL)	60	90	55
C4 (mg/dL)	10	20	6
Anti-dsDNA (IU/mL)	100	70	125
BP (mmHg)	118/78	120/80	119/79
Weight (lbs)	148	150	155

This is a hypothetical case study. This resource is intended to help you determine the types of patients who may be appropriate for treatment with LUPKYNIS. This representation was not designed to assess efficacy for an individual patient subgroup.

BID=twice daily; BP=blood pressure; eGFR=estimated glomerular filtration rate; SLE=systemic lupus erythematosus.

LUPKYNIS™ (voclosporin) can help patients achieve greater outcomes vs standard of care (MMF + steroids) alone[1,2,a,b]

2.7x

more likely to achieve complete renal response with LUPKYNIS vs standard of care alone[c]

2x

faster proteinuria reductions vs standard of care alone[d]

≤2.5 mg/day

by Week 16—efficacy achieved in the presence of low-dose steroids

To learn more about how LUPKYNIS can help your patients with lupus nephritis, **visit LUPKYNISpro.com**

[a]The AURORA Phase 3 trial was a randomized, double-blind, placebo-controlled trial of LUPKYNIS 23.7 mg BID in combination with MMF (target 2 g/day) and corticosteroids (n=179) vs placebo BID in combination with MMF and corticosteroids (n=178) in adults with class III or IV (alone or in combination with class V) or class V lupus nephritis. Efficacy was established on the basis of complete renal response at Week 52. Key secondary endpoints included complete renal response at Week 24, partial renal response (50% reduction in UPCR from baseline) at Weeks 24 and 52, time to UPCR ≤0.5 mg/mg, and time to 50% reduction in UPCR.[1,3]

[b]Complete renal response was achieved in 40.8% of patients with LUPKYNIS and 22.5% with control. Proteinuria reductions (UPCR ≤0.5 mg/mg) were achieved at a median time of 169 days with LUPKYNIS vs 372 days with control.[1]

[c]The primary efficacy endpoint of complete renal response was defined as a confirmed UPCR of ≤0.5 mg/mg; eGFR ≥60 mL/min/1.73 m^2 or no confirmed decrease from baseline in eGFR of >20% or no treatment- or disease-related eGFR-associated event at time of assessment; presence of sustained, low-dose steroids (≤10 mg prednisone from Weeks 44-52); and no administration of rescue medications. Proteinuria reduction was based on time to UPCR of ≤0.5 mg/mg.[1]

[d]Secondary endpoint in the AURORA Phase 3 trial.

Important Safety Information (cont.)

CONTRAINDICATIONS: LUPKYNIS is contraindicated in patients taking strong CYP3A4 inhibitors because of the increased risk of acute and/or chronic nephrotoxicity, and in patients who have had a serious/severe hypersensitivity reaction to LUPKYNIS or its excipients.

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CONTRAINDICATIONS: LUPKYNIS is contraindicated in patients taking strong CYP3A4 inhibitors because of the increased risk of acute and/or chronic nephrotoxicity, and in patients who have had a serious/severe hypersensitivity reaction to LUPKYNIS or its excipients.

WARNINGS AND PRECAUTIONS

Lymphoma and Other Malignancies: Immunosuppressants, including LUPKYNIS, increase the risk of developing lymphomas and other malignancies, particularly of the skin. The risk appears to be related to increasing doses and duration of immunosuppression rather than to the use of any specific agent.

Serious Infections: Immunosuppressants, including LUPKYNIS, increase the risk of developing bacterial, viral, fungal, and protozoal infections (including opportunistic infections), which may lead to serious, including fatal, outcomes.

Nephrotoxicity: LUPKYNIS, like other calcineurin inhibitors (CNIs), may cause acute and/or chronic nephrotoxicity. The risk is increased when CNIs are concomitantly administered with drugs associated with nephrotoxicity.

Hypertension: Hypertension is a common adverse reaction of LUPKYNIS therapy and may require antihypertensive therapy.

Neurotoxicity: LUPKYNIS, like other CNIs, may cause a spectrum of neurotoxicities: severe include posterior reversible encephalopathy syndrome (PRES), delirium, seizure, and coma; others include tremor, paresthesia, headache, and changes in mental status and/or motor and sensory functions.

Hyperkalemia: Hyperkalemia, which may be serious and require treatment, has been reported with CNIs, including LUPKYNIS. Concomitant use of agents associated with hyperkalemia may increase the risk for hyperkalemia.

QTc Prolongation: LUPKYNIS prolongs the QTc interval in a dose-dependent manner when dosed higher than the recommended lupus nephritis therapeutic dose. The use of LUPKYNIS in combination with other drugs that are known to prolong QTc may result in clinically significant QT prolongation.

Immunizations: Avoid the use of live attenuated vaccines during treatment with LUPKYNIS. Inactivated vaccines noted to be safe for administration may not be sufficiently immunogenic during treatment with LUPKYNIS.

Pure Red Cell Aplasia: Cases of pure red cell aplasia (PRCA) have been reported in patients treated with another CNI immunosuppressant. If PRCA is diagnosed, consider discontinuation of LUPKYNIS.

Drug-Drug Interactions: Avoid co-administration of LUPKYNIS and strong CYP3A4 inhibitors or with strong or moderate CYP3A4 inducers. Reduce LUPKYNIS dosage when co-administered with moderate CYP3A4 inhibitors. Reduce dosage of certain P-gp substrates with narrow therapeutic windows when co-administered.

ADVERSE REACTIONS

The most common adverse reactions (≥3%) were glomerular filtration rate decreased, hypertension, diarrhea, headache, anemia, cough, urinary tract infection, abdominal pain upper, dyspepsia, alopecia, renal impairment, abdominal pain, mouth ulceration, fatigue, tremor, acute kidney injury, and decreased appetite.

SPECIFIC POPULATIONS

Pregnancy/Lactation: May cause fetal harm. Advise not to breastfeed.

Renal Impairment: Not recommended in patients with baseline eGFR ≤45 mL/min/1.73 m^2 unless benefit exceeds risk. If used in this population, reduce LUPKYNIS dose.

Hepatic Impairment: For mild or moderate hepatic impairment, reduce LUPKYNIS dose. Avoid use with severe hepatic impairment.

Please see Prescribing Information including Boxed Warning and Medication Guide for LUPKYNIS.

References: 1. LUPKYNIS [package insert]. Rockville, MD: Aurinia Pharma U.S., Inc., 2021. **2.** Aurinia Pharma U.S., Inc. Data on file. **3.** Gibson K, Parikh S, Saxena A, et al; AURORA Study Group. AURORA phase 3 study demonstrates voclosporin statistical superiority over standard of care in lupus nephritis. Presented at: National Kidney Foundation virtual 2020 Spring Clinical Meetings; March 26-29, 2020.

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