Not an actual patient.

Is endoscopic management the most comprehensive approach for Sidney's low-grade UTUC?

Indications and Usage

JELMYTO® (mitomycin) for pyelocalyceal solution is indicated for the treatment of adult patients with low-grade Upper Tract Urothelial Cancer (LG-UTUC).

Important Safety Information

Contraindications

JELMYTO is contraindicated in patients with perforation of the bladder or upper urinary tract.

Ureteric Obstruction

Ureteric obstruction, including ureteral stenosis and hydronephrosis, occurred in patients receiving JELMYTO. Monitor patients for signs and symptoms of ureteric obstruction, including flank pain, and fever, and for changes in renal function. Patients who experience obstruction may require transient or long-term ureteral stents or alternative procedures. Withhold or permanently discontinue JELMYTO based on the severity of ureteric obstruction.

Please see additional Important Safety Information throughout and click here for Full Prescribing Information, Instructions for Pharmacy, and Instructions for Administration.

Jelmyto®
(mitomycin) for pyelocalyceal solution

SIDNEY'S CHARACTERISTICS*

- **Age:** 71
- **Tumor location:** Renal pelvis/ureter
- **Number of papillary tumors:** 3
- **Diameter of largest tumor:** 15 mm
- **History of LG-UTUC:** Yes
- **Previous renal ablative surgery:** Yes
- **ECOG PS:** 0

*Tumor characteristics based on latest UTUC diagnosis.

COMORBIDITIES

- BMI = 31 kg/m^2
- Hypertension

CASE HISTORY

- Last year, Sidney was treated with laser ablation for a low-grade papillary tumor in her left renal pelvis. She remained disease-free for 8 months
- Four months ago, she reported flank pain on her left side. She presented with microhematuria; urinary tract infection was ruled out
- Cystoscopy was unremarkable but CT urogram showed a 12 mm and 5 mm papillary lesion in the mid-pole calyx of her left renal pelvis and a 0.5 mm ureteral tumor
- A diagnostic ureteroscopy was performed and biopsy confirmed recurrence of low-grade UTUC. It was decided that Sidney would be treated in-clinic with laser ablation. However, she has tried this approach before and has asked what else can be done to support a durable treatment response

ECOG PS = Eastern Cooperative Oncology Group Performance Score.

OLYMPUS Study design: The efficacy of JELMYTO was investigated in the OLYMPUS Study (N=71), a phase 3 open-label, single-arm, multicenter trial in patients with treatment-naïve or recurrent low-grade non-invasive UTUC with ≥ 1 measurable papillary tumor 5 to 15 mm (partial resection/debulking was permitted if > 15 mm). Patients were treated with 6 instillations once a week. The dosage of JELMYTO was individualized based on volumetric measurements using pyelography with the intent to fill the renal pelvis (maximum dose was 15 mL or 60 mg mitomycin). CR was defined as complete absence of tumor lesions in the ipsilateral pyelocalyceal system at 3 months after initiation of JELMYTO by urine cytology, ureteroscopy, and biopsy (if warranted). The primary endpoint was CR. Secondary endpoint: durability of response at 12-month follow-up of CR evaluation.[2]

Important Safety Information (cont'd)

Bone Marrow Suppression

The use of JELMYTO can result in bone marrow suppression, particularly thrombocytopenia and neutropenia. The following tests should be obtained prior to each treatment: Platelet count, white blood cell count differential and hemoglobin. Withhold JELMYTO for Grade 2 thrombocytopenia or neutropenia. Permanently discontinue for Grade 3 or greater thrombocytopenia or neutropenia.

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Is a multimodal regimen with JELMYTO® appropriate for Sidney?

The OLYMPUS Study population included low-grade UTUC patients who were similar to Sidney[3,4]

- **52%** had a history of LG-UTUC
- **52%** had previous renal ablative surgery
- **66%** had pre-existing hypertension
- **34%** had BMI > 30 kg/m^2

JELMYTO, as part of a multimodal regimen, offers the potential for durable complete response[2,5†‡]

- 58% of patients achieved complete response (CR) at 3 months (n=71; 95% CI: 45, 69)[2]
- 82% durability of response at 12 months post CR (95% CI: 66, 91)[5§]
  - Estimated probability by Kaplan-Meier analysis that a patient will remain in CR for 12 months. At the 12-month assessment of durability (n=41): 23 patients remained in CR, 8 patients had a recurrence, and 10 patients were inevaluable[2]
  - Median duration of response was not reached, with a range of 0 - 18.8+ months[2]

†JELMYTO should not be instilled immediately following resection or ablation.

‡In the OLYMPUS Study, 37% of patients underwent tumor debulking during the 6 weeks preceding enrollment.[2]

Adverse reactions[2]

- The most common adverse reactions in ≥ 20% of patients treated with JELMYTO were ureteric obstruction, urinary tract infection, hematuria, flank pain, nausea, dysuria, renal dysfunction, vomiting, fatigue, and abdominal pain

Administered via ureteral catheter or nephrostomy tube in the clinic, ASC, or hospital as an outpatient procedure[3]

- Instilled as a chilled liquid once weekly for 6 weeks[2]

ASC = ambulatory surgery center; BMI = body mass index.

For patients like Sidney,

Take a multimodal approach with JELMYTO for a durable, primary treatment[1]

Important Safety Information (cont'd)

Embryo-Fetal Toxicity

Based on findings in animals and mechanism of action, JELMYTO can cause fetal harm when administered to a pregnant woman. In animal reproduction studies, administration of mitomycin resulted in teratogenicity. Advise females of reproductive potential to use effective contraception during treatment with JELMYTO and for 6 months following the last dose. Advise male patients with female partners of reproductive potential to use effective contraception during treatment with JELMYTO and for 3 months following the last dose.

Common Adverse Reactions

The most common adverse reactions in ≥ 20% of patients treated with JELMYTO were ureteric obstruction, urinary tract infection, hematuria, flank pain, nausea, dysuria, renal dysfunction, vomiting, fatigue, and abdominal pain.

Additional Adverse Reactions Information

Selected clinically relevant adverse reactions in < 10% and ≥ 2% of patients who received JELMYTO include urinary tract inflammation, bladder spasm, urosepsis, hypersensitivity, and instillation site pain.

Use in Specific Populations

Lactation

Because of the potential for serious adverse reactions in a breastfed child, advise women not to breastfeed during treatment with JELMYTO and for 1 week following the last dose.

Preparation and Administration Information

JELMYTO is for pyelocalyceal use only and not for intravenous use, topical use, or oral administration. JELMYTO must be prepared and administered by a healthcare provider. To ensure proper dosing, it is important to follow the preparation instructions found in the JELMYTO Instructions for Pharmacy and administration instructions found in the JELMYTO Instructions for Administration.

JELMYTO may discolor urine to a violet to blue color following the instillation procedure. Advise patients to avoid contact with urine for at least six hours post-instillation, to void urine sitting on a toilet, and to flush the toilet several times after use.

JELMYTO is a cytotoxic drug. Follow applicable special handling and disposal procedures.

§ Kaplan-Meier analysis estimates probability of durable response. It does not represent an actual percentage of patients. In the OLYMPUS trial, at the time of the 12-month assessment for durability, not all patients had a recurrence (patients may have still been in CR, died, or discontinued). The KM analysis accounts for these missing data. The analysis has potential limitations: the sample size was small (n=41) and median duration of response was not reached due to the limited number of recurrences (n=8); this may be reflective of a short follow-up time (12 months).

References: 1. Petros FG, Li R, Matin SF. Endoscopic approaches to upper tract urothelial carcinoma. *Urol Clin North Am.* 2018;45(2):267-286. **2.** JELMYTO [package insert]. Princeton, NJ: UroGen Pharma, Inc.; 2021. **3.** Kleinmann N, Matin SF, Pierorazio PM, et al. Primary chemoablation of low-grade upper tract urothelial carcinoma using UGN-101, a mitomycin-containing reverse thermal gel (OLYMPUS): an open-label, single-arm, phase 3 trial. *Lancet Oncol.* 2020;21(6):776-785. **4.** Data on file. UroGen Pharma, Inc., Princeton, NJ. **5.** Matin SF, Pierorazio PM, Kleinmann N, et al. Durability of response to primary chemoablation of low-grade upper tract urothelial carcinoma using UGN-101, a mitomycin-containing reverse thermal gel: OLYMPUS trial final report [published online: December 17, 2021]. *J Urol.* doi:10.1097/JU.0000000000002350

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UroGen® Pharma

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