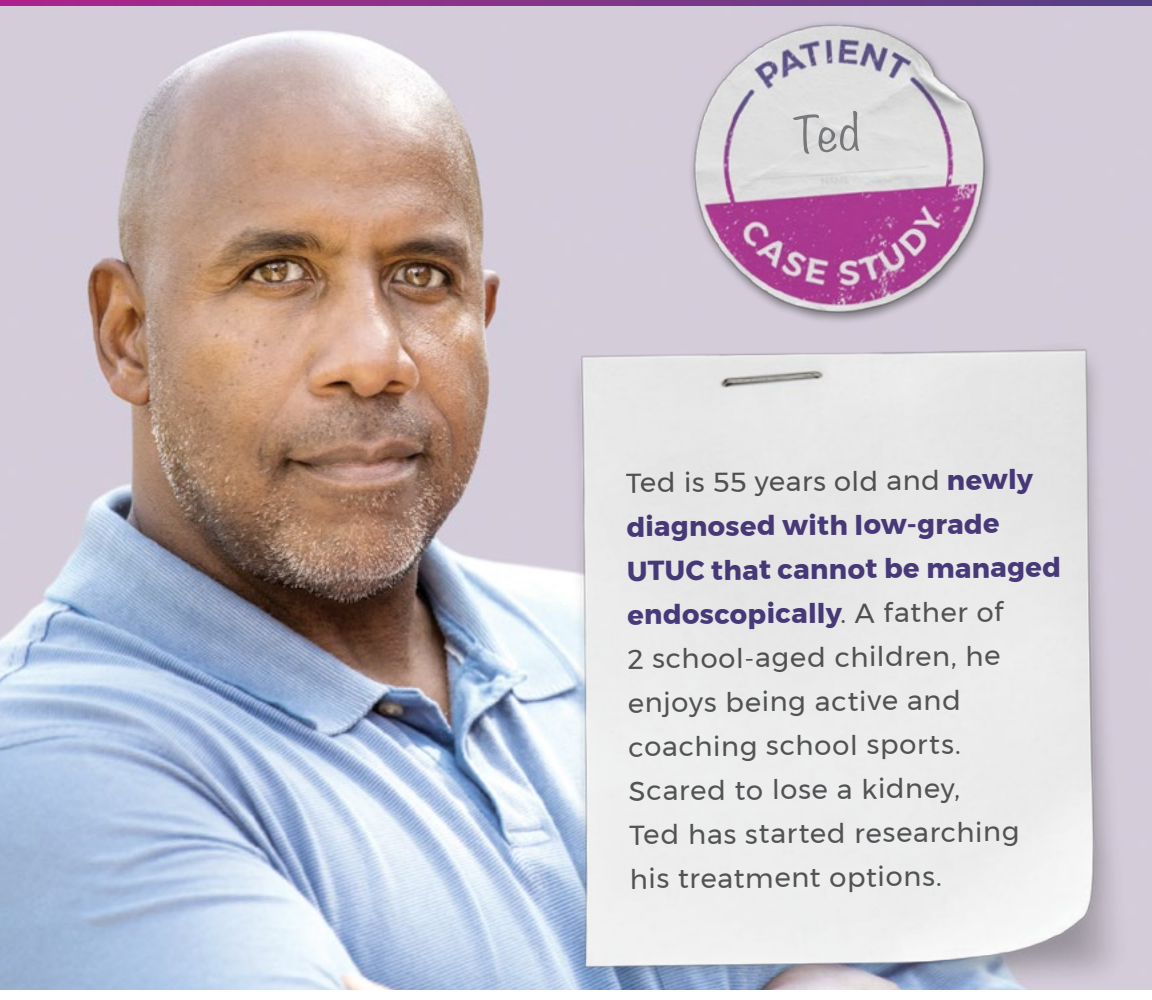

Not an actual patient.

With unresectable tumors, can Ted's primary multifocal disease be treated without surgery?

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

TED'S CHARACTERISTICS

- Age: **55**
- Number of papillary tumors: **2**
- Diameter of largest tumor: **15 mm**
- Total tumor burden: **23 mm**
- History of LG-UTUC disease: **no**
- Previous renal ablative surgery: **no**
- ECOG PS: **0**

COMORBIDITIES

- Former smoker (2 packs a day for 25 years; quit 10 years ago)
- Hypertension
- Gastroesophageal reflux disease

CASE HISTORY

- Ted recently reported several instances of hematuria and flank pain. Urinalysis confirmed hematuria and ruled out a urinary tract infection. Cystoscopy ruled out bladder cancer
- Retrograde urography showed a large filling defect and CT scan showed 2 papillary tumors in the lower pole of Ted's left renal pelvis that are endoscopically unresectable. Ureteropyeloscopy and biopsy confirmed low-grade upper tract urothelial carcinoma
- Ted is extremely anxious about surgery. He prefers a noninvasive procedure that will not require extensive recovery

*JELMYTO is instilled via the pyelocalyceal system in a procedure that spares the kidney.
CR = complete response; CT = computerized tomography; ECOG PS = Eastern Cooperative Oncology Group Performance Score; KM = Kaplan-Meier.

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 between 5-15 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.[1]

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.

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

JELMYTO GIVES NEWLY DIAGNOSED PATIENTS LIKE TED AN EFFECTIVE, NONSURGICAL OPTION[1,2]

The OLYMPUS Study population included low-grade UTUC patients with similar characteristics to Ted[2]

- **25%** were aged < 65 years
- **48%** had tumors that were unreachable by laser
- **48%** did not have a history of LG-UTUC disease

Chemoablate with JELMYTO to spare Ted's kidney for tomorrow[1]*

- 58% of patients achieved complete response at 3 months (n=71; 95% CI: 45, 69)
  - A prespecified subgroup analysis of patients with unresectable tumors demonstrated a CR rate of 59% (n=20/34; 95% CI: 41, 75)[2]

82% durability of response at 12 months post-CR (95% CI: 66, 91)[1,3†]

- Estimated probability by KM 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
  - Median duration of response was not reached, with a range of 0-18.8+ months

Adverse reactions[1]

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

A simple outpatient procedure can help patients like Ted feel comfortable with their treatment course[1,2]

- 6 weekly instillations, without the recovery time of surgery
- General anesthesia is not required
  - Used in 37% of patients for at least one instillation during the treatment period. Local anesthesia or sedation was used at the discretion of the physician

For patients like Ted,
CHEMOABLATE NOW, SPARE THE KIDNEY FOR TOMORROW[1]*

Jelmyto®
(mitomycin) for pyelocalyceal solution

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, flank pain, urinary tract infection, hematuria, abdominal pain, fatigue, renal dysfunction, nausea, dysuria, and vomiting.

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 hazardous 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. JELMYTO [package insert]. Princeton, NJ: UroGen Pharma, Inc.; 2022. **2.** 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. **3.** 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. *J Urol.* 2022;207(4):779-788.

Please click here for Full Prescribing Information, Instructions for Pharmacy, and Instructions for Administration.

UroGen® Pharma

Jelmyto® (mitomycin) for pyelocalyceal solution

JELMYTO® and UroGen® are registered trademarks of UroGen Pharma, Ltd.
© 2023 UroGen Pharma, Inc. All rights reserved. US-JEL-00566 01/23