FOR LOW-GRADE UPPER TRACT UROTHELIAL CANCER (UTUC) IN ADULT PATIENTS[1]

THE FIRST AND ONLY FDA-APPROVED TREATMENT FOR LOW-GRADE UTUC[1]

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CHEMOABLATE NOW

SPARE THE KIDNEY FOR TOMORROW[1]*

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.

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.

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.

Please see additional Important Safety Information on the reverse and click here for Full Prescribing Information for JELMYTO.

IN THE OLYMPUS STUDY,†

JELMYTO treatment in patients with low-grade UTUC achieved:

58% Complete Response
(95% CI: 45, 69)
of patients treated with JELMYTO achieved a Complete Response (CR)[1]

N=71

84% Durability of Response
(95% CI: 71, 97)
estimated based on an interim Kaplan-Meier analysis at 12 months post-CR[2,3]

- The OLYMPUS Study is ongoing. At the time of data cutoff, **19** patients remained in CR, **7** had disease recurrence, and **9** patients continued to be followed for 12-month duration of response[1]
- The most common adverse reactions (≥20%) reported were ureteric obstruction, flank pain, urinary tract infection, hematuria, renal dysfunction, fatigue, nausea, abdominal pain, dysuria, and vomiting[1]

*JELMYTO is instilled via the pyelocalyceal system in a procedure that spares the kidney.

† Study design: The efficacy of JELMYTO was investigated in the ongoing 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. CR was defined as complete absence of tumor lesions at 3 months after initiation of treatment and evaluated via 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]

CI=confidence interval.

Important Safety Information (cont'd)

Common Adverse Reactions

The most common adverse reactions in ≥ 20% of patients treated with JELMYTO were ureteric obstruction, flank pain, urinary tract infection, hematuria, renal dysfunction, fatigue, nausea, abdominal pain, 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 cytotoxic drug. Follow applicable special handling and disposal procedures.

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

References: 1. JELMYTO [package insert]. Princeton, NJ: UroGen Pharma, Inc.; 2020. **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. https://doi.org/10.1016/S1470-2045(20)30147-9. Accessed May 5, 2020. **3.** Data on file. UroGen Pharma, Inc., Princeton, NJ.

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