

FDA Approves Jelmyto for Upper Tract Urothelial Cancer

More than half of patients treated with mitomycin experienced complete tumor remission.

April 17, 2020 By [Food and Drug Administration \(FDA\)](#)

FDA approves mitomycin for low-grade upper tract urothelial cancer

On April 15, 2020, the Food and Drug Administration approved mitomycin (Jelmyto, UroGen Pharma) for adult patients with low-grade upper tract urothelial cancer (LG-UTUC).

Efficacy determination was based on OLYMPUS (NCT02793128), an ongoing, single-arm, multicenter trial enrolling 71 patients with treatment-naïve or recurrent low-grade non-invasive UTUC with at least one measurable papillary tumor located above the ureteropelvic junction. Patients who had larger tumors could have had prior tumor debulking. Patients received weekly JELMYTO 4 mg per mL instillations via ureteral catheter or nephrostomy tube for 6 weeks. For patients with a complete response (CR) at 3 months, instillations were to be administered monthly for a maximum of 11 additional instillations.

The major efficacy outcome measures were CR and CR durability. CR was defined as complete absence of tumor lesions 3 months after Jelmyto initiation and was assessed by urine cytology and ureteroscopy. If warranted, a biopsy was performed.

Forty-one patients (58%) achieved a CR three months following treatment initiation and were continued in follow-up; 29 patients received at least one dose of maintenance therapy.

Durability of response in those with CRs was evaluated at 3, 6, 9 and 12 months, following the CR determination. Seven patients had documented recurrences and nineteen patients remained in CR at 12-months following CR determination. The median response duration had not been reached (range: 0, 18.8+ months).

The most common adverse reactions ($\geq 20\%$) in patients who received Jelmyto were ureteric obstruction, flank pain, urinary tract infection, hematuria, renal dysfunction, fatigue, nausea, abdominal pain, dysuria, and vomiting. Ureteric obstruction occurred in 58% of those receiving Jelmyto and required ureteral stent placement in 88% of these patients.

The recommended Jelmyto dose is 4 mg per mL instilled via ureteral catheter or nephrostomy tube, with total instillation volume based on volumetric measurements using pyelography, not

exceeding 15 mL (60 mg mitomycin).

[View full prescribing information for Jelmyto.](#)

This review used the [Assessment Aid](#), a voluntary submission from the applicant to facilitate the FDA's assessment.

FDA granted this application priority review, fast track and breakthrough therapy designation. A description of FDA expedited programs is in the [Guidance for Industry: Expedited Programs for Serious Conditions-Drugs and Biologics](#).

Healthcare professionals should report all serious adverse events suspected to be associated with the use of any medicine and device to FDA's [MedWatch Reporting System](#) or by calling 1-800-FDA-1088.

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