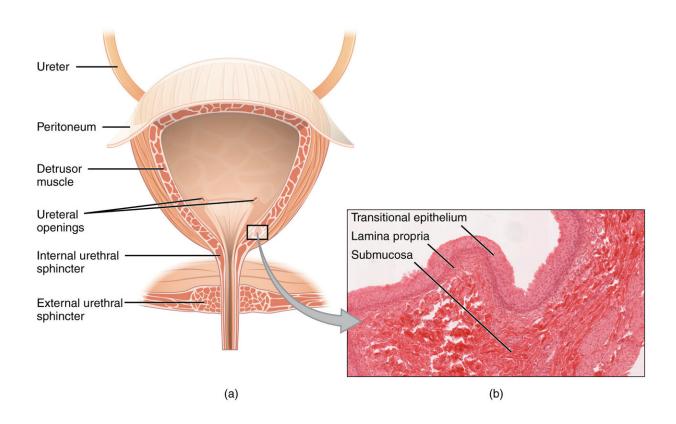


Research reveals promising new combination treatment for bladder cancer patients

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Researchers from Memorial Sloan Kettering Cancer Center (MSK) shared a promising treatment option for bladder cancer patients today at The European Society for Medical Oncology (ESMO) Congress 2022. Jonathan E. Rosenberg, MD, medical oncologist and Chief of the Genitourinary Oncology Service at MSK, presented results from a phase



1/2 trial (EV-103/KEYNOTE-869 Cohort K), which found that nearly two thirds (64.5%) of previously untreated cisplatin-ineligible patients with locally advanced or metastatic urothelial cancer who were treated with enfortumab vedotin plus pembrolizumab saw their tumors shrink and 15.6% had their tumors disappear completely.

"The results of this <u>cohort</u> of the EV-103 trial are very promising for <u>bladder cancer</u> patients," said Dr. Rosenberg. "MSK has been on the forefront of developing and testing antibody-drug conjugates, such as enfortumab vedotin, either alone or in combination with checkpoint inhibitors, such as pembrolizumab, in bladder cancer. While immunotherapy has gotten more attention in recent years, <u>antibody-drug conjugates</u> might end up making a bigger positive impact in treating bladder cancer, especially in combination with checkpoint inhibitors as shown in this trial."

In the phase 1b/2 EV-103 clinical trial, patients treated with enfortumab vedotin and pembrolizumab (n=76), had a 64.5% confirmed objective response rate (ORR) (95% CI: 52.7 to 75.1) per RECIST v1.1 by blinded independent central review (BICR), the primary endpoint of Cohort K, with 10.5% of patients experiencing a complete response and 53.9% of patients experiencing a partial response. The median duration of response (DOR) per BICR was not reached (95% CI: 10.25 months, -). Encouraging preliminary progression-free and overall survival results were observed, although these data remain immature at this time. Overall, the results were generally consistent with previously reported efficacy and safety results of the EV-103/KEYNOTE-869 dose-escalation cohort and expansion Cohort A.

Enfortumab vedotin plus pembrolizumab was granted Breakthrough Therapy Designation from The U.S. Food and Drug Administration (FDA) in February 2020 for patients who had unresectable advanced or metastatic urothelial carcinoma. Prior to this approval, Dr. Rosenberg



led multiple <u>clinical trials</u> resulting in FDA approval of enfortumab vedotin in 2019 for patients with locally advanced or metastatic bladder cancer who cannot have surgery or whose disease persists despite prior treatment with immunotherapy and chemotherapy.

More information: Conference:

www.esmo.org/meetings/esmo-congress-2022

Provided by Memorial Sloan Kettering Cancer Center

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