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NCCN Guidelines Panel: Cervical/Uterine Cancers

Dear NCCN Cervical/Uterine Cancers Panel:

Please find the enclosed reference for your review regarding Herceptin® (trastuzumab)¹:

Request:

Consider the enclosed information on the use of Herceptin in addition to carboplatin-paclitaxel in patients with uterine serous carcinomas that overexpress human epidermal growth factor receptor 2/neu (HER2/neu) presented at the 2018 Society of Gynecologic Oncology Annual Meeting on Women's Cancer on March 24th in New Orleans for your drug information updating needs.

Key Takeaways:

Fader, et.al. was a multicenter, single-arm, randomized Phase II trial conducted to evaluate the efficacy and safety of adding Herceptin to carboplatin/paclitaxel vs. carboplatin/paclitaxel alone in 61 patients with advanced or recurrent uterine serous carcinoma who overexpressed HER2/neu.¹ With a median follow-up of 10 months, the trial met its primary endpoint of progression free survival (PFS) [12.6 months in the Herceptin arm vs. 8 months in the control arm P=0.005; HR, 0.44].¹ At the time of analysis data for the secondary end-point of overall survival (OS) had not yet matured.

There was no significant difference in toxicity between the two arms and no new safety signals were identified.^{1,2}

Currently, we are not aware of any additional clinical trials (completed, ongoing, or planned) for Herceptin in uterine serous carcinomas.

FDA Clearance:

- Herceptin is not FDA-approved for use in patients with uterine serous carcinomas that overexpress HER2/neu.
- Please refer to the product prescribing information for the full FDA-approved indications and safety information, available at: https://www.gene.com/download/pdf/herceptin_prescribing.pdf

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Thank you for your consideration and I hope this information is helpful to you. If you have any questions, please contact me directly.

Respectfully submitted,
Ayesha Ahmed PharmD

References:

1. Fader AN, Roque DM, Siegel E, et.al. Randomized Phase II Trial of Carboplatin-Paclitaxel Versus Carboplatin-Paclitaxel-Trastuzumab in Uterine Serous Carcinomas That Overexpress Human Epidermal Growth Factor Receptor 2/neu. J Clin Oncol. 2018 Mar 27;JCO2017765966
2. Herceptin (trastuzumab) [package insert]. Genentech Inc; South San Francisco, CA 2018.