Toxicity data reveal no safety concerns with S/N1806 bladder cancer trial

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Updated toxicity data from the ongoing SWOG/NRG 1806 clinical trial, which tests combining chemoradiation therapy with immunotherapy in patients with localized muscle-invasive bladder cancer, reveal no significant safety concerns with the combination.

S/N1806 study team member Sameer G. Jhavar, MD, Ph.D., of Baylor Scott and White Health, of Temple, Texas, will present a safety report on 213 patients as an oral presentation at the 2022 annual meeting of the American Society for Radiation Oncology (ASTRO) in San Antonio on October 25.

Patients enrolled in the phase 3 S/N1806 trial have non-metastatic muscle-invasive bladder cancer. All patients on the trial are randomized 1:1 to one of two treatment arms. Patients on both arms are treated with standard trimodality therapy, which combines endoscopic surgery to maximally remove the bladder tumor with chemoradiation therapy. The half of patients on the investigational arm also receive the immunotherapy drug atezolizumab in combination with the chemoradiation, every three weeks for six months.

The lead author on the report is Parminder Singh, MD, a SWOG investigator at the Mayo Clinic in Phoenix, Arizona.

"This is a randomized phase 3 clinical trial investigating the addition of immunotherapy to bladder-preserving trimodality chemoradiation therapy," Singh said. "There is no sign of significant toxicity concerns in the investigative arm, which suggests the regimen is safe, and the trial continues to accrue very well. If positive, the trial may lead to improved treatment options for patients with bladder cancer by which they can preserve their bladder."

Among the 213 patients assessed, 113 received the trimodality therapy plus atezolizumab combination. The remaining 100 patients were randomized to the control arm of trimodality therapy alone.

Overall, 65 of the 113 patients (58 percent) on the atezolizumab arm reported Grade 3 or higher toxicities, compared to 44 of 100 patients (44 percent) on the control arm. Most toxicities were hematological and

were not considered to be immune related by the treating physician. However, a number of known immune-related adverse events of atezolizumab were reported at Grade 3 or higher on the investigational arm.

An earlier pre-specified safety analysis of the first 80 patients enrolled to the trial also showed no significant increase in toxicity on the investigational arm as compared to the control arm. The S/N1806 trial continues to accrue well and is expected to reach its enrollment goal of 475 patients within the next two years. It is the largest study investigating bladder-preserving therapy in North America.

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