CCTG BL12 presented at ASCO

Randomized phase II trial comparing nab-paclitaxel (Nab-P) to paclitaxel (P)

Wednesday, June 6, 2018

Bladder cancer hit the world stage with an oral presentation at ASCO this past weekend. The presentation of the results of the study was given by Dr. Srikala Sridhar, BL12 Study Chair, at the general meeting in Chicago. Bladder cancer is the 5th most common cancer in Canada with 9000 new cases annually. For patients with advanced disease who progress on first line chemotherapy, options include immunotherapy or taxane-based chemotherapy.

"We previously showed encouraging activity with nab-paclitaxel, a solvent-free formulation of paclitaxel. To confirm this, we performed a large international, randomized study comparing nab-paclitaxel to paclitaxel. We found that both drugs had similar efficacy and quality of life, but there was more toxicity with nab-paclitaxel. We also found that response rates with the taxanes (~20%) are actually similar to that seen with immunotherapy, meaning that paclitaxel remains an importan
t therapeutic option in second line, but further research is still needed as we don't yet have a cure for this disease," says Srikala Sridhar, Study Chair, BL12, Medical Oncologist, Princess Margaret Hospital, Associate Professor of Medicine, University of Toronto.

This investigator-initiated study was completed in collaboration with the Australian and New Zealand Urogenital and Prostate Cancer Trials Group (ANZUP)
Abstract 4505 (219679): CCTG BL12: Randomized phase II trial comparing nab-paclitaxel (Nab-P) to paclitaxel (P) in patients (pts) with advanced urothelial cancer progressing on or after a platinum containing regimen (NCT02033993).

**Methods:** Canadian Cancer Trials Group led a multicentre randomized phase II trial comparing Nab-P 260mg/m2 IV q21 days to P 175mg/m2 IV q21 days in pts with advanced urothelial cancer progressing after one line of platinum-based therapy. The primary endpoint was progression free survival (PFS); secondary endpoints included overall survival (OS), response rate (RR), adverse events (AEs) using CTC AE V4.03 and QOL (EORTC-C15-PAL, FACT-Taxane). A sample size of 199 pts was selected to detect target PFS HR of 0.67 using a 1-sided 5% level test with 81% power. Stratification factors included ECOG, liver mets, LN only mets, Hb level and ?6mo from last platinum regimen. **Results:** 199 pts from Canada and Australia were enrolled from 2014-2017 with median age 67y, including 72% males, 30% liver mets, 84% ECOG 0/1 and 55% ?6mo from last platinum therapy. Relative dose intensity ?90% was 78% for Nab-P vs 67% for P. With median follow up 16.4mo, median PFS for Nab-P was 3.4mo vs 3.0mo for P (HR 0.92, 90%CI 0.68-1.23, p = 0.31); median OS for Nab-P was 7.5mo vs 8.8mo for P (HR 0.95, 90%CI 0.70- 1.30, p = 0.40). RR were similar, Nab-P 21% vs P 23% (p = 0.97). Rate of Grade(Gr)3+ all causality AEs was 67% for Nab-P vs 46% for P (p = 0.009); peripheral sensory neuropathy was 74% (Gr3+ 7%) for Nab-P vs 66% (Gr3+ 3%) for P (p = 0.27 (all grades), 0.33(Grd3+)). There were no significant differences in mean scores in any domain of QOL between Nab-P and P. **Conclusions:** Nab-P has similar efficacy and QOL compared to P as second line therapy in advanced urothelial cancer. Gr3+ all causality AEs were higher in the Nab-P arm. Clinical trial information: [NCT02033993](https://clinicaltrials.gov/show/NCT02033993)