TPS5130 Poster Session

# A phase II study of niraparib (N), abiraterone acetate (AA) plus prednisone (P) for Hispanic/Latino (HL) and non-Hispanic Black (NHB) patients with metastatic hormone sensitive prostate cancer (mHSPC) and deleterious homologous recombination repair alterations (HRRa; HARMONY).

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**Background:** Patients with prostate cancer and deleterious HRRa have poorer prognosis but derive benefit from poly (ADP-ribose) polymerase (PARP) inhibition. However, prevalence of HRRa and response to PARP inhibition are less well defined in racial/ethnic minorities. We designed the HARMONY trial to evaluate the efficacy of N/AA/P in HL and NHB patients with mHSPC and deleterious HRRa. **Methods:** This multicenter, open label, phase II study is open through the Hoosier Cancer Research Network in the United States. The trial enrolls patients who self-identify as HL or NHB and have mHSPC with HRRa including *BRCA 1/2*, *BRIP1*, *CHEK2*, *FANCA*, *PALB2*, *RAD51B*, and/or *RAD54L*. Eligible patients will have hormone sensitive, treatment naïve or minimally treated prostate cancer (i.e., bicalutamide $\leq$ 45 days, androgen deprivation therapy [ADT] $\pm$ AA plus P $\leq$ 45 days allowed). Prostate cancer variants, other therapy in mHSPC setting, or symptomatic brain metastases are exclusionary. Enrolled patients will receive 24 weeks (w) of ADT plus N/AA dual action tablet (DAT) plus P, followed by an adaptive approach based on prostate specific antigen (PSA) response. Subjects in Arm A (PSA $>$ 4.0 ng/mL at 24 w) can continue ADT/N/AA/P for max 2 years or stop N and escalate therapy to ADT/AA/P plus 6 cycles of docetaxel followed by standard of care (SOC) therapy. Subjects in Arm B (PSA $\leq$ 4.0 ng/mL at 24 w) will continue ADT/N/AA/P for a total of 12 months. At 12 months in Arm B, subjects with PSA $\geq$ 0.2 ng/mL will continue ADT/N/AA/P for max 2 years, and subjects achieving PSA $<$ 0.2 ng/mL have the option to continue ADT/N/AA/P for max 2 years or discontinue all therapy with the option to start SOC treatment at disease progression. PSA decline to $<$ 0.2 ng/mL at 24w (primary endpoint) will be evaluated for each racial/ethnicity group against a historic rate of 50%. Thirty patients per racial/ethnic cohort will give 80% power at 0.1 significance to determine noninferiority with a no-inferiority margin of 0.185. Estimating 5% drop out, 64 patients will be enrolled (n=32 HL and n=32 NHB). Key secondary/exploratory endpoints include PSA reduction $\geq$ 90%, overall response rate, PSA/radiographic progression free survival, overall survival, time to subsequent anti-cancer therapy, quality of life and safety. Key genomic correlatives will be evaluated. ClinicalTrials.gov: NCT06392841. Study support of drug and funding: Janssen Scientific Affairs LLC. Clinical trial information: NCT06392841. Research Sponsor: Janssen Scientific Affairs LLC.