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Health-related quality of life (HRQoL) outcomes from the NIAGARA trial of perioperative durvalumab (D) plus neoadjuvant chemotherapy (NAC) in muscle-invasive bladder cancer (MIBC)

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Background

In the phase 3 NIAGARA trial (NCT03732677), patients (pts) with MIBC treated with perioperative D + NAC with radical cystectomy (RC) demonstrated statistically significant and clinically meaningful improvement in event-free survival (EFS) and overall survival (OS) and a numerical increase in pCR rate vs NAC and RC alone. Here we report HRQoL outcomes.

Methods

Cisplatin-eligible pts with MIBC (cT2-T4aN0/1M0) planned for RC were randomised 1:1 to 4 cycles of neoadjuvant D (1500 mg IV Q3W) + NAC (cisplatin + gemcitabine IV Q3W) followed by RC then 8 cycles of adjuvant D monotherapy (1500 mg IV Q4W) (D arm) or NAC followed by RC alone (comparator [C] arm). HRQoL was measured using the European Organization for Research and Treatment of Cancer 30-item quality of life questionnaire (QLQ-C30) as a secondary endpoint. Global health status/quality of life (GHS/QoL), physical functioning, fatigue and pain were prespecified priority subscales. Change from baseline (CFB) and time to definitive deterioration (TTDD) were assessed. HRQoL per EuroQol 5-dimension, 5-level (EQ-5D-5L) visual analogue scale (VAS) was an exploratory endpoint.

Results

QLQ-C30 baseline compliance was ≥82% in both arms. Mean baseline scores were similar between arms. For prespecified subscales, pts experienced clinically meaningful deterioration (≥10 point change) prior to adjuvant therapy, which then returned to baseline levels in the adjuvant phase, with no significant difference in CFB between the D arm and C arm (Table). A trend toward prolonged TTDD in the D arm was observed (Table). EQ-5D-5L VAS compliance was ≥78% at baseline in both arms. VAS CFB followed a similar pattern to QLQ-C30, with no notable differences between arms. Table: 3069MO

QLQ-C30 subscales	D arm vs C arm: overall LSM CFB, difference between arms (95% CI)	D arm Median TTDD, months (IQR)	C arm Median TTDD, months (IQR)	D arm vs C arm TTDD, HR [†] (95% CI)
GHS/QoL*	1.6 (-0.44, 3.69)	52.4 (7.8–NR)	44.4 (2.9–NR)	0.80 (0.64, 1.00)
Physical functioning*	1.2 (-0.80, 3.17)	49.7 (7.2–NR)	39.4 (3.6–48.9)	0.86 (0.70, 1.07)
Fatigue [†]	-0.9 (-3.25, 1.52)	36.4 (2.8–59.6)	30.5 (1.8–61.7)	0.94 (0.77, 1.14)
Pain [†]	-2.1 (-4.44, 0.16)	57.1 (12.6–NR)	56.3 (9.1–NR)	0.80 (0.63, 1.02)

*LSM CFB positive difference favours D.†LSM CFB negative difference favours D.‡HR <1 favours D.CI, confidence interval; HR, hazard ratio; IQR, interquartile range; LSM, least squares mean, NR, not reached.

Conclusions

Addition of perioperative D to NAC with RC provided clinically meaningful EFS and OS benefit without detriment to patient-reported HRQoL, further supporting this regimen as a new treatment for MIBC.

Clinical trial identification

NCT03732677; November 06, 2018.

Editorial acknowledgement

Medical writing assistance was provided by Lewis Cawkwell, PhD, of Parexel, funded by AstraZeneca.

Legal entity responsible for the study

AstraZeneca.

Funding

AstraZeneca.

Disclosure

M.S. van der Heijden: Financial Interests, Institutional, Advisory Board: AstraZeneca, BMS, Janssen, MSD, Seagen, Pfizer, Astellas; Financial Interests, Institutional, Funding, Investigator-initiated trial: Roche, MSD, BMS, AstraZeneca, 4SC; Financial Interests, Institutional, Steering Committee Member, Local PI + SSC member: Seagen, MSD, BMS, AstraZeneca; Financial Interests, Institutional, Steering Committee Member, Local PI + study co-PI: Janssen. T.B. Powles: Financial Interests, Personal, Advisory Board: AstraZeneca, Bristol Myers-Squibb, Exelixis, Incyte, Ipsen, Merck, Novartis, Pfizer, Seattle Genetics, Merck Serono, Astellas, Johnson & Johnson, Eisai, Roche, MSD; Financial Interests, Personal, Other, Travel/Accommodation/Expenses: Roche, Pfizer, MSD, AstraZeneca, Ipsen; Financial Interests, Personal, Other, Sponsorship for Uromigos Podcast: Mashup Ltd; Financial Interests, Institutional, Other, honoraria: Gilead; Financial Interests, Institutional, Research Grant: AstraZeneca, Roche, Bristol Myers-Squibb, Exelixis, Ipsen, Merck, MSD, Seattle Genetics, Novartis, Pfizer, Merck Serono, Astellas, Johnson & Johnson, Eisai; Financial Interests, Institutional, Other, Honoraria: Gilead. M.D. Galsky: Financial Interests, Personal, Advisory Board: Janssen, Merck, Pfizer, EMD Serono, AstraZeneca, SeaGen, AbbVie, Gilead; Financial Interests, Institutional, Steering Committee Member: Merck, Bristol Myers-Squibb, Seagen; Financial Interests, Institutional, Coordinating PI: AstraZeneca. J.W.F. Catto: Financial Interests, Institutional, Speaker, Consultant, Advisor: AstraZeneca; Financial Interests, Personal, Speaker, Consultant, Advisor: BMS, Pfizer, Roche, Ferring, Janssen, Photocure, Medac, Ipsen; Financial Interests, Institutional, Research Grant: Roche; Financial Interests, Personal, Advisory Board: Gilead Sciences, QED Therapeutics, Roche, Steba Biotech, Urogen ; Financial Interests, Personal, Other, Trustee: Bladder Cancer UK. J. Meeks: Financial Interests, Personal, Speaker, Consultant, Advisor: Merck, AstraZeneca, Urogen, Janssen, Immunity Bio, Pfizer, Prokarium ; Financial Interests, Personal, Speaker's Bureau: Olympus, Carden Jennings, Lugpa; Financial Interests, Personal, Advisory Board: Axio, Medscape. R. Zukov: Financial Interests, Personal, Speaker, Consultant, Advisor: AstraZeneca, Johnson & Johnson, Merck, Novartis, Roche, Pfizer, Aegean, Biocad; Financial Interests, Institutional, Research Funding: AstraZeneca, BMS, Johnson & Johnson, MSD, Novartis, Roche. S.A. Hussain: Financial Interests, Institutional, Research Funding: CR UK, MRC/NIHR, UBH charities , CCC charities , North West Cancer Research , Weston Park Cancer Charity , Bayer, Janssen, Boehringer Ingelheim, Ingelheim, Pierre Fabre, Eli Lilly; Financial Interests, Personal, Research Funding: Roche; Financial Interests, Personal, Speaker, Consultant, Advisor: Roche , MSD, AZ, BMS, Janssen, GSK, Astellas, Pfizer, Bayer, Merck, Pierre Fabre, Sotio, Gilead. A. Necchi: Financial Interests, Institutional, Research Grant: Merck, AstraZeneca, Ipsen, BMS, Gilead; Financial Interests, Personal, Steering Committee Member: Janssen, Astellas, AstraZeneca, Merck, Gilead, BMS, Bicycle Therapeutics, Daiichi Sankyo; Financial Interests, Coordinating PI: Incyte, Genenta Sciences; Financial Interests, Personal, Coordinating PI: Catalym; Financial Interests, Personal, Funding: Samsung Bioepis; Non-Financial Interests, Leadership Role: Global society of Rare Genitourinary Tumors (GSRGT). M.J. Schnabel: Financial Interests, Personal, Speaker, Consultant, Advisor: Astellas, AstraZeneca, Apogepha, Bayer, BMS, Eisai, Gilead, Ipsen, JNJ, Medac, Merck, MSD, Novartis, Pfizer, Roche; Financial Interests, Personal, Other, Travel/accommodation/expenses: JNJ, Ipsen, Pfizer. A.G.A. Lui: Financial Interests, Speaker, Consultant, Advisor: AstraZeneca, Pfizer, Merck, MSD, Novartis, Takeda, Eli Lilly, AMGEN, Johnson & Johnson, Roche, Hi-Eisai, AstraZeneca, Sandoz, Guardant, Taiho. C. Cernadas: Financial Interests, Personal, Full or part-time Employment: AstraZeneca. K. Bigos: Financial Interests, Personal, Full or part-time Employment: AstraZeneca. S. Hois: Financial Interests, Personal, Full or part-time Employment: AstraZeneca. H. Nishiyama: Financial Interests, Institutional, Research Funding: Astellas, Chugai, Johnson & Johnson; Financial Interests, Personal, Speaker, Consultant, Advisor: Astellas, AstraZeneca, BMS, Ono Pharmaceutical, Johnson & Johnson , MSD, Nippon Kayaku. All other authors have declared no conflicts of interest.