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ALBAN: A phase III, randomized, open-label, international study of intravenous (iv) atezolizumab and intravesical Bacillus Calmette-Guérin (BCG) vs BCG alone in BCG-naïve high-risk, non-muscle-invasive bladder cancer (NMIBC)

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Background

The standard of care for high-risk NMIBC patients (pts) is transurethral resection of the bladder tumor followed by BCG intravesical instillations. ALBAN study aims to compare the combination of atezolizumab + BCG *vs* BCG for BCG-naïve pts with high-risk NMIBC.

Methods

Eligible pts with histologically confirmed NMIBC with high-risk features, no prior BCG therapy, ECOG PS 0-2 were randomized 1:1 to BCG (6-weekly instillations followed by 3-weekly maintenance instillations at 3, 6, 12 months [Arm A]) or atezolizumab (1200 mg; IV; q3w for up to 1 year) combined with BCG delivered as in Arm A (Arm B). Randomization was stratified by presence of CIS. The primary endpoint was event-free survival (EFS). Key secondary endpoints included high-grade recurrence-free survival (HG RFS), overall survival (OS), and safety.

Results

A total of 517 pts was randomized to Arm A (N=255) or Arm B (N=262). Mean age was 67.4 years (range: 29-91); 85.5% of pts were men; most pts had an ECOG PS of 0 (88.6%); 39.1% were diagnosed with the presence of carcinoma in situ (CIS) at inclusion, including 7.0% of pure CIS; 39.5% had T1 tumor and 21.3% had Ta tumor high-grade/grade 3. At the data cut-off date (9 Jan 2025), the median follow-up was 35.3 months (range: 0-60). There was no statistically significant difference in EFS between arms (HR=0.98 (95% CI: 0.71-1.36), P=0.9106). EFS results were consistent across all prespecified subgroups including CIS population. The HG RFS was similar between arms (stratified HR, 1.06 (95% CI: 0.72-1.54); P = 0.7804). Median OS were not reached. Grade ≥3 treatment-related adverse events occurred in 8.8% and 22.7% of patients in Arm A and Arm B. The most common were cystitis (1.2%) in Arm A, and urinary tract disorder (2.0%) and pollakiuria (1.2%) in Arm B.

Conclusions

ALBAN trial did not demonstrate benefit from adding atezolizumab to BCG in BCG-naive high-risk NMIBC.

Clinical trial identification

NCT03799835.

Legal entity responsible for the study

Unicancer.

Funding

Roche.

Disclosure

M. Roupret: Financial Interests, Personal, Advisory Board: Roche, Astellas, Janssen, Bayer, Intuitive, BMS, AstraZeneca, Ferring, CURIUM; Non-Financial Interests, Leadership Role: CCAFU chairman; Non-Financial Interests, Project Lead, Editor in Chief European Urology Oncology: European Association Urology. G. Pignot: Financial Interests, Personal, Advisory Board: Janssen, Pfizer, Oncodiag; Financial Interests, Personal, Invited Speaker: Janssen, BMS, Ipsen, Bayer, Photocure, Accord Healthcare; Financial Interests, Institutional, Other, financial support for a research project on sexology: astellas; Financial Interests, Institutional, Advisory Board: BMS; Financial Interests, Institutional, Invited Speaker: AZ. L. 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