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Sacituzumab govitecan (SG) versus treatment of physician's choice (TPC) in patients (pts) with previously treated metastatic triple-negative breast cancer (mTNBC): Final results from the phase 3 ASCENT study

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Background: Treatment goals for pts with metastatic breast cancer include extended survival and improved quality of life (QoL). SG received FDA approval for pts with mTNBC who received ≥2 prior chemotherapies (at least 1 in the metastatic setting). In the pivotal phase 3 ASCENT study (NCT02574455), SG demonstrated a significant survival benefit over single-agent chemotherapy TPC in the primary analysis (Bardia *NEJM* 2021) and QoL (Loibl ESMO 2021). With additional follow up, we present the final data on efficacy, including overall survival (OS), safety, and QoL.
Methods: Pts with mTNBC refractory or relapsing after ≥2 prior chemotherapies with at least 1 in the metastatic setting were randomized 1:1 to receive SG (10 mg/kg IV on days 1 and 8, every 21 days) or TPC (capecitabine, eribulin, vinorelbine, or gemcitabine) until disease progression or unacceptable toxicity. Primary endpoint was progression-free survival (PFS), key secondary endpoints included OS, safety, and health-related QoL. Safety was analyzed in pts who received ≥1 dose of study drug.
Result: At final database lock SG (n=235) vs TPC (n=233) significantly improved median PFS (5.6 vs 1.7 mo; $P<0.0001$) and median OS (12.1 vs 6.7 mo; $P<0.0001$). In the safety population (n=482), key treatment-related grade ≥3 adverse events with SG (n=258) vs TPC (n=224) were diarrhea (11% vs 0.4%), neutropenia (52% vs 33%), anemia (8% vs 5%), and febrile neutropenia (6% vs 2%).
Discussion: SG showed clinically meaningful and statistically significant improvements vs TPC in OS and QoL.
Conclusion: The analysis based on the final database lock of ASCENT confirms the superior survival outcomes of SG over single-agent chemotherapy, with a manageable safety profile and improvement in QoL for pts with mTNBC in the 2L+ setting. These findings reinforce SG as an effective treatment option for this pt population.

Indication of source:
1 Bardia et al. NEJM 2021; 384:1529-1541
2 Loibl et al. ESMO 2021; abstract 257P

Disclosure Statement: The authors declare that there are conflicts of interest. The connections were submitted to the congress organizer KUKM GmbH and KUKM can disclose them if needed.

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The SURVIVE-study – a randomized phase 3 liquid-biopsy based breast cancer surveillance trial

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Background: After patients with early breast cancer have completed primary therapy, current guidelines limit routine surveillance in breast cancer survivors to clinical surveillance and breast imaging. Screening for distant metastases is initiated only in patients with specific symptoms.
Methods/Clinical Trial Design: The SURVIVE study, funded by the German Federal Ministry of Education and Research, is a controlled phase 3 superiority trial, in which 3500 patients with intermediate-to-high risk early breast cancer will be randomized 1:1 to guideline-based standard follow-up surveillance versus intensified, liquid-biopsy guided surveillance. Patients in the liquid-biopsy guided surveillance arm will be repeatedly tested for the standard tumor markers CA 27.29, CA 125 and CEA, as well as for circulating tumor cells and circulating tumor DNA. Pre-specified abnormal findings of any of the liquid biopsy markers indicative of minimal residual disease (MRD) will trigger staging examinations including a CT scan of the chest and abdomen and a bone scan. If the tumor staging shows disease recurrence, the patients will receive guideline-based diagnostic measures and treatment; otherwise, the patients will continue liquid-biopsy marker testing.

The two primary objectives of the SURVIVE study are to determine whether the intensified, liquid-biopsy guided breast cancer surveillance leads to a better overall survival and to assess the lead-time effect compared to the standard surveillance arm. Secondary objectives include the evaluation of invasive disease-free survival, distant disease-free survival, quality of life, as well as sensitivity and specificity for the detection of MRD by the liquid biopsy markers.
Result: n/a
Discussion: n/a
Conclusion: The SURVIVE study is a long-awaited breast cancer surveillance trial based on promising liquid biopsy markers, which – if successful - will lead to a paradigm shift in the current follow-up care of medium and high-risk early breast cancer survivors.

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